

No	Question / Answer	(1)-(2) 05	(3)-(11) REPEAT
		Code	Skip to
Q8	What factors influence the choice of Factor VIII treatment for haemophilia A patients?		
	<b>PROBE FULLY</b>	(12)	
	Recombinant vs human plasma-derived	1	
	Well-established/standard product	2	
	Albumin/protein content	3	
	Efficacy/response rates	4	
	Duration of effect/half life	5	
	Speed of response/effect	6	
	Safety (unspecified)	7	
	Lack of adverse reactions	8	
	Lack of albumin reaction	9	
	Lack of (viral) contamination	0	
	Lack of immunity/resistance/lack of inhibitor development	X	
	Range of potencies/vial sizes	V	
		(13)	
	Diluent/infusion volume	1	
	Storage (refrigeration vs room temperature)	2	
	Shelf-life	3	
	Supply/availability	4	
	Delivery to patient's home	5	
	Manufacturer (e.g. reputation/involvement in haemophilia)	6	
	(Good) relationship with the manufacturer	7	
	Ease of reconstitution	8	
	Speed of reconstitution	9	
	Ease of administration	0	
	Cost	X	
		(14)	
		(15)	
		(16)	
		(17)	
	Other (please specify)	X	
	-----		
	-----		
	Do not know	V	

No	Question / Answer	Code	Score
Q9	How satisfied are you with the currently available recombinant Factor VIII products? Would you say you were <b>SHOW CARD 1</b>	(18)	1
	Very dissatisfied	1	
	Fairly dissatisfied	2	
	Neither satisfied nor dissatisfied	3	
	Fairly satisfied	4	
	Very satisfied	5	
	Don't know	V	
Q10	What improvements would you like to see made to recombinant Factor VIII products? <b>PROBE FULLY</b>	(19)	
	Reduced use of albumin/protein	1	
	Improved efficacy/response	2	
	Longer lasting effect/longer half-life	3	
	Improved speed of response/effect	4	
	Improved safety (unspecified)	5	
	Fewer adverse reactions	6	
	Reduced/no albumin reaction	7	
	Reduced/no (viral) contamination	8	
	Reduced immunity/resistance/inhibitor development	9	
	Higher potencies/larger vial sizes	0	
		(20)	
	Reduced volume of diluent/infusion	1	
	Indication for continuous infusion	2	
	Improved storage (refrigeration not required)	3	
	Longer shelf-life	4	
	Improved supply/availability	5	
	Clearer storage instructions	6	
	Improved packaging/less wastage of ancillary products	7	
	Improved/easier reconstitution	8	
	Faster reconstitution	9	
	Improved/easier administration	0	
	Reduced cost	X	
		(21)	
		(22)	(23)
		(24)	
	Other (please specify)	X	
	----- ----- -----		
	Don't know	V	

No	Question / Answer	Code	Skip to
	<p><b>HAND DOCTOR SHOW CARD A</b></p> <p>THIS CARD LISTS SEVERAL FEATURES ON WHICH POTENTIAL NEW RECOMBINANT PRODUCTS FOR HAEMOPHILIA A MIGHT DIFFER PLEASE TAKE A FEW MINUTES TO READ OVER THE FEATURES AND THEIR VARIOUS LEVELS, AS THIS INFORMATION WILL MAKE THE FOLLOWING EXERCISE RUN MORE SMOOTHLY</p> <p><b>ALLOW RESPONDENT TIME TO READ ALL INFORMATION ON THE CARD</b></p> <p>I HAVE HERE 32 CARDS, EACH DESCRIBING A POTENTIAL RECOMBINANT FACTOR VIII PRODUCT WITH A UNIQUE COMBINATION OF FEATURES NO TWO CARDS ARE EXACTLY THE SAME FOR THE PURPOSE OF THIS EXERCISE, PLEASE IMAGINE THAT THESE 32 POTENTIAL PRODUCTS ARE THE ONLY ONES AVAILABLE FOR THE TREATMENT OF HAEMOPHILIA A</p> <p><b>HAND DOCTOR SHUFFLED CARDS</b></p> <p>CONSIDERING YOUR PATIENTS WITH HAEMOPHILIA A, PLEASE SORT THESE 32 POTENTIAL PRODUCTS INTO <u>3 PILES</u> ACCORDING TO YOUR LIKELIHOOD TO PRESCRIBE THEM ONE PILE SHOULD CONTAIN THOSE PRODUCTS THAT YOU WOULD BE <u>MOST</u> LIKELY TO USE, ONE THOSE PRODUCTS THAT YOU <u>MIGHT</u> CONSIDER USING AND ONE THOSE PRODUCTS THAT YOU WOULD BE <u>LEAST</u> LIKELY TO USE YOU CAN HAVE ANY NUMBER OF CARDS IN EACH OF THE 3 PILES</p> <p>ASSUME THESE PRODUCTS ARE EQUAL ON ANY FEATURES THAT ARE NOT INCLUDED ON THE CARDS</p> <p>THIS IS A VERY IMPORTANT PART OF THE STUDY PLEASE TAKE YOUR TIME AS WE REALISE THIS TASK REQUIRES CAREFUL CONSIDERATION</p> <p><b>WAIT UNTIL THE DOCTOR HAS SORTED ALL THE CARDS INTO THREE PILES, THEN CONTINUE</b></p> <p>I WOULD NOW LIKE YOU TO RANK THESE 32 CARDS FROM TOP TO BOTTOM, STARTING WITH THE PRODUCT YOU ARE MOST LIKELY TO PRESCRIBE FOR HAEMOPHILIA A ON THE TOP, THROUGH TO THE PRODUCT YOU ARE LEAST LIKELY TO PRESCRIBE ON THE BOTTOM</p> <p>PLEASE BEGIN BY RANKING THESE PRODUCTS IN THE "MOST LIKELY" PILE</p> <p><b>AFTER "MOST LIKELY" PILE IS RANKED, ASK THE DOCTOR TO CONTINUE WITH THE PILE OF PRODUCTS HE/SHE "MIGHT PRESCRIBE" AND THEN FINALLY RANK THE "LEAST LIKELY" PILE.</b></p> <p><b>ONCE THE DOCTOR HAS FINISHED SAY</b></p> <p>PLEASE READ OUT THE NUMBERS OF THE CARDS IN THE ORDER YOU HAVE ARRANGED THEM THE FIRST NUMBER YOU READ OUT SHOULD BE THE PRODUCT YOU ARE <u>MOST</u> LIKELY TO PRESCRIBE AND THE LAST NUMBER YOU READ OUT SHOULD BE THE PRODUCT YOU ARE <u>LEAST</u> LIKELY TO PRESCRIBE</p> <p><b>RECORD RESPONSES ON NEXT PAGE</b></p>		

(1)-2	3-
CS	REPEAT

WRITE IN EACH NUMBER IN THE APPROPRIATE COLUMN BELOW

RANK	PRODUCT CARD NUMBER	RANK	PRODUCT CARD NUMBER
1 (MOST LIKELY)	(12) (13)	17	(44) (45)
	(14) (15)	18	(46) (47)
2	(16) (17)	19	(48) (49)
3	(18) (19)	20	(50) (51)
4	(20) (21)	21	(52) (53)
5	(22) (23)	22	(54) (55)
6	(24) (25)	23	(56) (57)
7	(26) (27)	24	(58) (59)
8	(28) (29)	25	(60) (61)
9	(30) (31)	26	(62) (63)
10	(32) (33)	27	(64) (65)
11	(34) (35)	28	(66) (67)
12	(36) (37)	29	(68) (69)
13	(38) (39)	30	(70) (71)
14	(40) (41)	31	(72) (73)
15	(42) (43)	32 (LEAST LIKELY)	(74) (75)
16			

		(1)-(2)	(3)-(11)
		07	REPEAT
No	Question / Answer	Code	Skip to
Q11	Considering the potential product that you ranked as the one you would be most interested in using, what are your reasons for ranking it first? <b>PROBE FULLY</b>	(12)	
		(13)	
		(14)	
Q12	Considering the potential product that you ranked as the one you would be most likely to use, how interested would you be in using it in the haemophilia A patients treated at this centre? Would you say you were <b>SHOW CARD 2</b>	(15)	
	Not at all interested	1	
	Not very interested	2	
	Neither interested nor disinterested	3	
	Fairly interested	4	
	Very interested	5	
	Don't know	V	
Q13	Considering the potential product that you ranked as the one you would be most likely to use, would you be willing to advocate paying a price premium for that product?	(16)	Q14 THANK AND CLOSE
	Yes	1	
	No	2	
	Don't know	V	
Q14	What percentage price increase over currently available recombinant products would you consider to be acceptable?	(20)	Q15 THANK AND CLOSE
	(17) (18) (19) % enter percentage	X	
	Depends	V	
	Don't know		
	<b>GO TO Q16 IF 'DEPENDS', OTHERWISE THANK AND CLOSE</b>		

No	Question / Answer	Case	Score
Q15	On what would the acceptable level of price increase depend? <b>PROBE FULLY</b>		
		(21)	
		(22)	
		(23,	

THANK AND CLOSE

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## **CARD A**

### **Doctors**

#### ***Human or animal derived protein***

- used in manufacturing (culturing) and in the final formulation (for stabilising)
- used in manufacturing (culturing), but not in the final formulation (for stabilising)
- not used at all

#### ***Continuous infusion***

- an approved indication
- product has capability, but not approved (label indication)
- not possible (to be used for continuous infusion)

#### ***Diluent volume per vial***

- 2.5ml
- 5ml
- 10ml

#### ***Higher number of activity units per vial***

- 1,000 i u per vial
- 1,250 i u per vial
- 1,500 i u per vial
- 2,000 i u per vial

#### ***Assay issue***

- requires one-stage assay
- requires chromogenic assay (not available in every hospital)

#### ***Room temperature storage***

- Cannot be stored at room temperature (requires refrigeration)
- 3 months
- 6 months
- 1 year
- 2+ years

#### ***rFVIII molecule***

- full length
- B-domain deleted

GH001353



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**DOCTOR - CARD 1**

***Human or animal derived protein***

- used in manufacturing (culturing), but not in the final formulation (for stabilising)

***Continuous infusion***

- an approved indication

***Diluent volume per vial***

- 5ml

***Higher number of activity units per vial***

- 1,250 i u per vial

***Assay issue***

- requires one-stage assay

***Room temperature storage***

- 6 months

***rFVIII molecule***

- full length

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**DOCTOR - CARD 2**

***Human or animal derived protein***

- used in manufacturing (culturing) and in the final formulation (for storage)

***Continuous infusion***

- an approved indication

***Diluent volume per vial***

- 5ml

***Higher number of activity units per vial***

- 1,000 i u per vial

***Assay issue***

- requires chromogenic assay (not available in every hospital)

***Room temperature storage***

- 3 months

***rFVIII molecule***

- B-domain deleted

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**DOCTOR - CARD 3**

*Human or animal derived protein*  
➤ not used at all

*Continuous infusion*  
➤ not possible (to be used for continuous infusion)

*Diluent volume per vial*  
➤ 5ml

*Higher number of activity units per vial*  
➤ 1,500 i u per vial

*Assay issue*  
➤ requires one-stage assay

*Room temperature storage*  
➤ 2+ years

*rFVIII molecule*  
➤ full length

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## **DOCTOR - CARD 4**

***Human or animal derived protein***

- not used at all

***Continuous infusion***

- not possible (to be used for continuous infusion)

***Diluent volume per vial***

- 5ml

***Higher number of activity units per vial***

- 2,000 i u per vial

***Assay issue***

- requires chromogenic assay (not available in every hospital)

***Room temperature storage***

- Cannot be stored at room temperature (requires refrigeration)

***rFVIII molecule***

- B-domain deleted

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**DOCTOR - CARD 5**

***Human or animal derived protein***

- not used at all

***Continuous infusion***

- product has capability, but not approved (label indication)

***Diluent volume per vial***

- 10ml

***Higher number of activity units per vial***

- 1,250 i u per vial

***Assay issue***

- requires chromogenic assay (not available in every hospital)

***Room temperature storage***

- 3 months

***rFVIII molecule***

- full length

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**DOCTOR – CARD 6**

*Human or animal derived protein*

- not used at all

*Continuous infusion*

- product has capability, but not approved (label indication)

*Diluent volume per vial*

- 10ml

*Higher number of activity units per vial*

- 1,000 i u per vial

*Assay issue*

- requires one-stage assay

*Room temperature storage*

- 6 months

*rFVIII molecule*

- B-domain deleted

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**DOCTOR - CARD 7**

***Human or animal derived protein***

- used in manufacturing (culturing), but not in the final formulation (for stabilising)

***Continuous infusion***

- not possible (to be used for continuous infusion)

***Diluent volume per vial***

- 10ml

***Higher number of activity units per vial***

- 1,500 i u per vial

***Assay issue***

- requires chromogenic assay (not available in every hospital)

***Room temperature storage***

- Cannot be stored at room temperature (requires refrigeration)

***rFVIII molecule***

- full length

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**DOCTOR - CARD 8**

***Human or animal derived protein***

- used in manufacturing (culturing) and in the final formulation (for stabilising)

***Continuous infusion***

- not possible (to be used for continuous infusion)

***Diluent volume per vial***

- 10ml

***Higher number of activity units per vial***

- 2,000 i u per vial

***Assay issue***

- requires one-stage assay

***Room temperature storage***

- 2+ years

***rFVIII molecule***

- B-domain deleted



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**DOCTOR - CARD 9**

***Human or animal derived protein***

- used in manufacturing (culturing) and in the final formulation (for stabilising)

***Continuous infusion***

- an approved indication

***Diluent volume per vial***

- 2.5ml

***Higher number of activity units per vial***

- 1,250 i.u. per vial

***Assay issue***

- requires one-stage assay

***Room temperature storage***

- Cannot be stored at room temperature (requires refrigeration)

***rFVIII molecule***

- full length

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**DOCTOR - CARD 10**

***Human or animal derived protein***

- used in manufacturing (culturing), but not in the final formulation (for stabilising)

***Continuous infusion***

- an approved indication

***Diluent volume per vial***

- 2.5ml

***Higher number of activity units per vial***

- 1,000 i.u. per vial

***Assay issue***

- requires chromogenic assay (not available in every hospital)

***Room temperature storage***

- 2+ years

***rFVIII molecule***

- B-domain deleted

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**DOCTOR - CARD 11**

*Human or animal derived protein*

➤ not used at all

*Continuous infusion*

➤ not possible (to be used for continuous infusion)

*Diluent volume per vial*

➤ 2.5ml

*Higher number of activity units per vial*

➤ 1,500 i u per vial

*Assay issue*

➤ requires one-stage assay

*Room temperature storage*

➤ 3 months

*rFVIII molecule*

➤ full length

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**DOCTOR - CARD 12**

*Human or animal derived protein*

- not used at all

*Continuous infusion*

- not possible (to be used for continuous infusion)

*Diluent volume per vial*

- 2.5ml

*Higher number of activity units per vial*

- 2,000 i u per vial

*Assay issue*

- requires chromogenic assay (not available in every hospital)

*Room temperature storage*

- 6 months

*rFVIII molecule*

- B-domain deleted

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**DOCTOR - CARD 13**

*Human or animal derived protein*

- not used at all

*Continuous infusion*

- product has capability, but not approved (label indication)

*Diluent volume per vial*

- 10ml

*Higher number of activity units per vial*

- 1,250 i u per vial

*Assay issue*

- requires chromogenic assay (not available in every hospital)

*Room temperature storage*

- 2+ years

*rFVIII molecule*

- full length

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**DOCTOR - CARD 14**

*Human or animal derived protein*  
➤ not used at all

*Continuous infusion*  
➤ product has capability, but not approved (label indication)

*Diluent volume per vial*  
➤ 10ml

*Higher number of activity units per vial*  
➤ 1,000 i u per vial

*Assay issue*  
➤ requires one-stage assay

*Room temperature storage*  
➤ Cannot be stored at room temperature (requires refrigeration)

*rFVIII molecule*  
➤ B-domain deleted

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**DOCTOR - CARD 15**

***Human or animal derived protein***

- used in manufacturing (culturing) and in the final formulation (for stabilising)

***Continuous infusion***

- not possible (to be used for continuous infusion)

***Diluent volume per vial***

- 10ml

***Higher number of activity units per vial***

- 1,500 i u per vial

***Assay issue***

- requires chromogenic assay (not available in every hospital)

***Room temperature storage***

- 6 months

***rFVIII molecule***

- full length

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**DOCTOR - CARD 16**

***Human or animal derived protein***

- used in manufacturing (culturing), but not in the final formulation (for stabilising)

***Continuous infusion***

- not possible (to be used for continuous infusion)

***Diluent volume per vial***

- 10ml

***Higher number of activity units per vial***

- 2,000 i u per vial

***Assay issue***

- requires one-stage assay

***Room temperature storage***

- 3 months

***rFVII molecule***

- B-domain deleted



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**DOCTOR - CARD 17**

***Human or animal derived protein***

- used in manufacturing (culturing), but not in the final formulation (for stabilising)

***Continuous infusion***

- not possible (to be used for continuous infusion)

***Diluent volume per vial***

- 10ml

***Higher number of activity units per vial***

- 1,000 i u per vial

***Assay issue***

- requires chromogenic assay (not available in every hospital)

***Room temperature storage***

- 1 year

***rFVII molecule***

- full length

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**DOCTOR - CARD 18**

***Human or animal derived protein***

- used in manufacturing (culturing) and in the final formulation (for stabilising)

***Continuous infusion***

- not possible (to be used for continuous infusion)

***Diluent volume per vial***

- 10ml

***Higher number of activity units per vial***

- 1,250 i u per vial

***Assay issue***

- requires one-stage assay

***Room temperature storage***

- 3 months

***rFVIII molecule***

- B-domain deleted

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**DOCTOR - CARD 19**

*Human or animal derived protein*  
➤ not used at all

*Continuous infusion*  
➤ an approved indication

*Diluent volume per vial*  
➤ 10ml

*Higher number of activity units per vial*  
➤ 2,000 i u per vial

*Assay issue*  
➤ requires chromogenic assay (not available in every hospital)

*Room temperature storage*  
➤ 2+ years

*rFVIII molecule*  
➤ full length

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**DOCTOR - CARD 20**

*Human or animal derived protein*  
➤ not used at all

*Continuous infusion*  
➤ an approved indication

*Diluent volume per vial*  
➤ 10ml

*Higher number of activity units per vial*  
➤ 1,500 i u per vial

*Assay issue*  
➤ requires one-stage assay

*Room temperature storage*  
➤ Cannot be stored at room temperature (requires refrigeration)

*rFVIII molecule*  
➤ B-domain deleted

J500398  
Version 3 (Final)  
23/11/1999

**DOCTOR - CARD 21**

*Human or animal derived protein*  
➤ not used at all

*Continuous infusion*  
➤ not possible (to be used for continuous infusion)

*Diluent volume per vial*  
➤ 5ml

*Higher number of activity units per vial*  
➤ 1,000 i u per vial

*Assay issue*  
➤ requires one-stage assay

*Room temperature storage*  
➤ 3 months

*rFVIII molecule*  
➤ full length

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**DOCTOR - CARD 22**

*Human or animal derived protein*

- not used at all

*Continuous infusion*

- not possible (to be used for continuous infusion)

*Diluent volume per vial*

- 5ml

*Higher number of activity units per vial*

- 1,250 i u per vial

*Assay issue*

- requires chromogenic assay (not available in every hospital)

*Room temperature storage*

- 1 year

*rFVIII molecule*

- B-domain deleted

J500398  
Version 3 (Final)  
23/11/1999

**DOCTOR - CARD 23**

***Human or animal derived protein***

- used in manufacturing (culturing), but not in the final formulation (for stabilising)

***Continuous infusion***

- product has capability, but not approved (label indication)

***Diluent volume per vial***

- 5ml

***Higher number of activity units per vial***

- 2,000 i u per vial

***Assay issue***

- requires one-stage assay

***Room temperature storage***

- Cannot be stored at room temperature (requires refrigeration)

***rFVIII molecule***

- full length

J500398  
Version 3 (Final)  
23/11/1999

**DOCTOR - CARD 24**

***Human or animal derived protein***

- used in manufacturing (culturing) and in the final formulation (for stabilising)

***Continuous infusion***

- product has capability but not approved (label indication)

***Diluent volume per vial***

- 5ml

***Higher number of activity units per vial***

- 1,500 i u per vial

***Assay issue***

- requires chromogenic assay (not available in every hospital)

***Room temperature storage***

- 2+ years

***rFVIII molecule***

- B-domain deleted



J500398

Version 3 (Final)  
23/11/1999

**DOCTOR - CARD 25**

***Human or animal derived protein***

- used in manufacturing (culturing) and in the final formulation (for stabilising)

***Continuous infusion***

- not possible (to be used for continuous infusion)

***Diluent volume per vial***

- 10ml

***Higher number of activity units per vial***

- 1,000 i u per vial

***Assay issue***

- requires chromogenic assay (not available in every hospital)

***Room temperature storage***

- Cannot be stored at room temperature (requires refrigeration)

***rFVIII molecule***

- full length

J500398  
Version 3 (Final)  
23/11/1999

**DOCTOR - CARD 26**

***Human or animal derived protein***

- used in manufacturing (culturing), but not in the final formulation (for stabilising)

***Continuous infusion***

- not possible (to be used for continuous infusion)

***Diluent volume per vial***

- 10ml

***Higher number of activity units per vial***

- 1,250 i u per vial

***Assay issue***

- requires one-stage assay

***Room temperature storage***

- 2+ years

***rFVIII molecule***

- B-domain deleted

J500398  
Version 3 (Final)  
23/11/1999

**DOCTOR - CARD 27**

*Human or animal derived protein*  
➤ not used at all

*Continuous infusion*  
➤ an approved indication

*Diluent volume per vial*  
➤ 10ml

*Higher number of activity units per vial*  
➤ 2,000 i u per vial

*Assay issue*  
➤ requires chromogenic assay (not available in every hospital)

*Room temperature storage*  
➤ 3 months

*rFVIII molecule*  
➤ full length

J500398  
Version 3 (Final)  
23/11/1999

**DOCTOR - CARD 28**

*Human or animal derived protein*  
➤ not used at all

*Continuous infusion*  
➤ an approved indication

*Diluent volume per vial*  
➤ 10ml

*Higher number of activity units per vial*  
➤ 1,500 i u per vial

*Assay issue*  
➤ requires one-stage assay

*Room temperature storage*  
➤ 1 year

*rFVIII molecule*  
➤ B-domain deleted

J500398  
Version 3 (Final)  
23/11/1999

**DOCTOR - CARD 29**

*Human or animal derived protein*

- not used at all

*Continuous infusion*

- not possible (to be used for continuous infusion)

*Diluent volume per vial*

- 2.5ml

*Higher number of activity units per vial*

- 1,000 IU per vial

*Assay issue*

- requires one-stage assay

*Room temperature storage*

- 2+ years

*rFVIII molecule*

- full length

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Version 3 (Final)  
23/11/1999

**DOCTOR - CARD 30**

*Human or animal derived protein*  
➤ not used at all

*Continuous infusion*  
➤ not possible (to be used for continuous infusion)

*Diluent volume per vial*  
➤ 2.5ml

*Higher number of activity units per vial*  
➤ 1,250 i.u per vial

*Assay issue*  
➤ requires chromogenic assay (not available in every hospital)

*Room temperature storage*  
➤ Cannot be stored at room temperature (requires refrigeration)

*rFVIII molecule*  
➤ B-domain deleted

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23/11/1999

**DOCTOR - CARD 31**

***Human or animal derived protein***

- used in manufacturing (culturing) and in the final formulation (for stabilising)

***Continuous infusion***

- product has capability, but not approved (label indication)

***Diluent volume per vial***

- 2.5ml

***Higher number of activity units per vial***

- 2,000 i u per vial

***Assay issue***

- requires one-stage assay

***Room temperature storage***

- 1 year

***rFVIII molecule***

- full length

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23/11/1999

**DOCTOR - CARD 32**

***Human or animal derived protein***

- used in manufacturing (culturing), but not in the final formulation (for stabilising)

***Continuous infusion***

- product has capability but not approved (label indication)

***Diluent volume per vial***

- 2.5ml

***Higher number of activity units per vial***

- 1,500 iu per vial

***Assay issue***

- requires chromogenic assay (not available in every hospital)

***Room temperature storage***

- 3 months

***rFVIII molecule***

- B-domain deleted



## **Appendix I**

### **(b) Nurses**

GH001387

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Version 3 (Final)

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CC	V No	Country	Serial	Nur

INTERNATIONAL HEALTH SURVEYS, LUDGATE HOUSE, 245 BLACKFRIARS ROAD, LONDON SE1 9UL

RECOMBINANT FVIII POSITIONING STUDY  
NURSE SCREENING QUESTIONNAIRE

Nurse name \_\_\_\_\_

Centre name \_\_\_\_\_

Address \_\_\_\_\_

(please print) \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Telephone No \_\_\_\_\_

\_\_\_\_\_

## INTRODUCTION

GOOD MORNING/AFTERNOON MY NAME IS \_\_\_\_\_ FROM INTERNATIONAL HEALTH SURVEYS, AN INDEPENDENT MARKET RESEARCH AGENCY BASED IN LONDON, WHICH SPECIALISE IN CONDUCTING SURVEYS AMONG MEMBERS OF THE MEDICAL PROFESSION AND PATIENTS

WE ARE CURRENTLY CONDUCTING AN INTERNATIONAL STUDY WITH DOCTORS, NURSES AND PATIENTS ON THE SUBJECT OF HAEMOPHILIA A.

THE INTERVIEW WILL LAST UP TO 45 MINUTES THE INFORMATION YOU PROVIDE WILL BE COMBINED WITH THAT OF YOUR COLLEAGUES NEITHER YOUR IDENTITY NOR THAT OF YOUR HOSPITAL WILL BE REVEALED TO ANY THIRD PARTY STRICT CONFIDENTIALITY IS ASSURED

WOULD YOU BE WILLING TO TAKE PART IN OUR SURVEY?

COULD I FIRST ASK YOU A FEW QUESTIONS TO ASSESS YOUR ELIGIBILITY FOR THIS SURVEY

No	Question / Answer	Code	Skip to
Q1	Do you work at/are you affiliated with a specialist/comprehensive haemophilia treatment centre?	(12)	
	Yes	1	CONTINUE
	No	2	THANK AND CLOSE
	Don't know	V	
Q2	Do you specialise in the treatment of haemophilia/bleeding disorders?	(13)	
	Yes	1	CONTINUE
	No	2	THANK AND CLOSE
	Don't know	V	

No	Question / Answer	Code	Screen
Q3	Are you involved in the treatment of haemophilia A?	(14)	
	Yes	1	CONTINUE
	No	2	THANK AND
	Don't know	V	CLOSE
Q4	Are you regularly involved in the reconstitution and administration of <u>recombinant</u> Factor VIII products for treating haemophilia A?	(15)	
	Yes	1	RECRUIT
	No	2	THANK AND
	Don't know	V	CLOSE

Version 3 (Final)  
23<sup>rd</sup> November 1999

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INTERNATIONAL HEALTH SURVEYS, LUDGATE HOUSE, 245 BLACKFRIARS ROAD, LONDON SE1 9UL

RECOMBINANT FACTOR VIII POSITIONING STUDY  
NURSE QUESTIONNAIRE - EUROPE

NAME \_\_\_\_\_ (PRINT)  
CENTRE NAME \_\_\_\_\_ (PRINT)  
ADDRESS \_\_\_\_\_ (PRINT)  
\_\_\_\_\_  
\_\_\_\_\_  
POST CODE \_\_\_\_\_ (PRINT)  
TEL NO \_\_\_\_\_

YEAR OF QUALIFICATION

(12) (13)

1	9		
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TYPE OF HOSPITAL

(15)

Public 1

Private 2

(16)

Teaching 1

Non-teaching 2

REGION (UK VERSION)

(14)

Northern & Yorkshire 1

Trent 2

North West 3

West Midlands 4

Anglia & Oxford 5

South & West 6

North Thames 7

South Thames 8

Wales 9

Scotland 0

Northern Ireland X

HOSPITAL BED SIZE

(17) (18) (19) (20)

--	--	--	--

(21)

Don't know V

COLUMNS (22)-(64) BLANK

TIME STARTED _____	DATE OF INTERVIEW	(65) (66)	(67) (68)	(69) (70)	(71) (72)	(73) (74)								
				9 9										
TIME FINISHED _____	INTERVIEWED BY	(75) (76) (77) (78) (79)												
		OUO (80)	1	2	3	4	5	6	7	8	9	O	X	V

RESPONDENT SIGNATURE FOR FEE.

INTERVIEWER SIGNATURE.

(signature) (signature)  
THIS INTERVIEW HAS BEEN CONDUCTED WITHIN THE TERMS OUTLINED BY THE MRS CODE OF CONDUCT

No	Question / Answer	Code	Score
Q1	<p>Approximately how many haemophilia patients in total are treated at this centre?</p> <p>(12) (13) (14)</p> <p><input type="text"/> <input type="text"/> <input type="text"/></p> <p>Don't know</p>	(15) V	
Q2	<p>Of all haemophilia patients treated at this centre, what percentage have haemophilia A and what percentage have haemophilia B?</p> <p>i) Haemophilia A</p> <p>(16) (17) (18) %</p> <p><input type="text"/> <input type="text"/> <input type="text"/></p> <p>Don't know</p> <p>ii) Haemophilia B</p> <p>(20) (21) (22) %</p> <p><input type="text"/> <input type="text"/> <input type="text"/></p> <p>None</p> <p>Don't know</p> <p><b>RESPONDENT MUST HAVE HAEMOPHILIA A PATIENTS (SEE SCREENER)</b> <b>ENSURE TOTAL EQUALS 100%</b></p>	(19) V  (23) O V	
	<b>EXPLAIN TO THE RESPONDENT THAT THE REST OF THE QUESTIONNAIRE CONCENTRATES EXCLUSIVELY ON HAEMOPHILIA A</b>		
Q3	<p>Thinking of all the haemophilia A patients treated at this centre, what percentage are adults and what percentage are paediatrics?</p> <p>i) Adults</p> <p>(24) (25) (26) %</p> <p><input type="text"/> <input type="text"/> <input type="text"/></p> <p>None</p> <p>Don't know</p> <p>ii) Paediatrics</p> <p>(28) (29) (30) %</p> <p><input type="text"/> <input type="text"/> <input type="text"/></p> <p>None</p> <p>Don't know</p> <p><b>ENSURE TOTAL EQUALS 100%</b></p>	(27) O V  (31) O V	

No	Question / Answer	Code	Skip to
Q4	<p><b>NOT TO BE ASKED IN EUROPE</b></p> <p style="text-align: right;">COLUMNS (32)-(43) BLANK</p>		
Q5	<p>Thinking of all the haemophilia A patients treated at this centre, what percentage currently use recombinant Factor VIII products and what percentage use human plasma derived Factor VIII products?</p> <p>i) Recombinant</p> <p style="text-align: center;">(44) (45) (46)</p> <p style="text-align: center;"><input type="text"/> <input type="text"/> <input type="text"/> %</p> <p style="text-align: right;">Don't know</p> <p>ii) Human plasma</p> <p style="text-align: center;">(48) (49) (50)</p> <p style="text-align: center;"><input type="text"/> <input type="text"/> <input type="text"/> %</p> <p style="text-align: right;">None Don't know</p> <p><b>RESPONDENT MUST HAVE PATIENTS ON RECOMBINANT PRODUCTS (SEE SCREENER) ENSURE TOTAL EQUALS 100%</b></p>	<p>(47) V</p> <p>(51) O V</p>	
Q6	<p><b>NOT TO BE ASKED IN EUROPE</b></p> <p style="text-align: right;">COLUMNS (52)-(65) BLANK</p>		
Q7	<p>Typically on how many occasions per week do you reconstitute/administer <u>recombinant</u> Factor VIII products?</p> <p style="text-align: center;">(56) (57) (58)</p> <p style="text-align: center;"><input type="text"/> <input type="text"/> <input type="text"/> occasions per week</p> <p style="text-align: right;">Don't know</p> <p><b>RESPONDENT MUST BE INVOLVED IN THE RECONSTITUTION/ ADMINISTRATION OF RECOMBINANT PRODUCTS (SEE SCREENER)</b></p>	<p>(59) V</p>	

No	Question / Answer	Code	Score
Q8a	Which specific brands of Factor VIII products are currently used in patients at this centre (both recombinant and human plasma derived products)?		
Q8b	<b>NOT TO BE ASKED IN EUROPE</b>		
	<p style="text-align: right;">Q8a Usage</p> <p style="text-align: center;">Recombinant</p> <p style="text-align: right;">(12)</p> <p style="text-align: right;">Bioclone 1</p> <p style="text-align: right;">Helixate 2</p> <p style="text-align: right;">Kogenate 3</p> <p style="text-align: right;">Recombinate 4</p> <p style="text-align: right;">Refacto 5</p> <p style="text-align: right;"><u>Human plasma</u> (13)</p> <p style="text-align: right;">Alphanate 1</p> <p style="text-align: right;">Benate 2</p> <p style="text-align: right;">Contact F 3</p> <p style="text-align: right;">Crosseight M 4</p> <p style="text-align: right;">Emoclot 5</p> <p style="text-align: right;">Fhandi 6</p> <p style="text-align: right;">Haemate-P/Humate P 7</p> <p style="text-align: right;">Haemoctin 8</p> <p style="text-align: right;">Hemofil M 9</p> <p style="text-align: right;">Immunate 0</p> <p style="text-align: right;">Innobrand X</p> <p style="text-align: right;">Koate DVI V</p> <p style="text-align: right;">(14)</p> <p style="text-align: right;">Kryobulin 1</p> <p style="text-align: right;">Monarc M 2</p> <p style="text-align: right;">Monoclone-P 3</p> <p style="text-align: right;">Nordate 4</p> <p style="text-align: right;">Octenate 5</p> <p style="text-align: right;">Octnativ M 6</p> <p style="text-align: right;">Profilate 7</p> <p style="text-align: right;">Replenate 8</p> <p style="text-align: right;">Uman 9</p> <p style="text-align: right;">(15)</p> <p style="text-align: right;">Other (specify) X</p>		
	COLUMNS (16)-(76) BLANK		



No	Question / Answer	(1)-(2) 12	(3)-(11) REPEAT
		Code	Skip to
Q9	What factors influence the choice of Factor VIII treatment for haemophilia A patients?		
	<b>PROBE FULLY</b>	(12)	
	Recombinant vs human plasma-derived	1	
	Well-established/standard product	2	
	Albumin/protein content	3	
	Efficacy/response rates	4	
	Duration of effect/half life	5	
	Speed of response/effect	6	
	Safety (unspecified)	7	
	Lack of adverse reactions	8	
	Lack of albumin reaction	9	
	Lack of (viral) contamination	0	
	Lack of immunity/resistance/lack of inhibitor development	X	
	Range of potencies/vial sizes	V	
		(13)	
	Diluent/infusion volume	1	
	Storage (refrigeration vs room temperature)	2	
	Shelf-life	3	
	Supply/availability	4	
	Delivery to patient's home	5	
	Manufacturer (e.g. reputation/involvement in haemophilia)	6	
	(Good) relationship with the manufacturer	7	
	Ease of reconstitution	8	
	Speed of reconstitution	9	
	Ease of administration	0	
	Cost	X	
		(14)	
		(15)	
		(16)	
		(17)	
	Other (please specify)	X	
	-----		
	-----		
	Don't know	V	

No	Question / Answer	Code	Score
Q10	How important are the following factors in the choice of Factor VIII treatment for haemophilia A patients? Please use a 10 point rating scale where 1 equals "not at all important" and 10 equals "extremely important"		
	<div> <div>Not at all important</div> <div>Extremely important</div> </div> <div> <div>1</div><div>2</div><div>3</div><div>4</div><div>5</div><div>6</div><div>7</div><div>8</div><div>9</div><div>10</div> </div>	OK	
	Recombinant vs human plasma-derived	V	18
	Well-established/standard product	V	19
	Albumin/protein content	V	20
	Efficacy/response rates	V	21
	Duration of effect/half-life	V	22
	Speed of response/effect	V	23
	Safety (unspecified)	V	24
	Lack of adverse reactions	V	25
	Lack of albumin reaction	V	26
	Lack of (viral) contamination	V	27
	Lack of immunity/resistance/inhibitor development	V	28
	Range of potencies/vial sizes	V	29
	Diluent/infusion volume	V	30
	Storage (refrigeration vs room temperature)	V	31
	Shelf-life	V	32
	Supply/availability	V	33
	Delivery to patient's home	V	34
	Manufacturer (i.e. reputation/involvement in haemophilia)	V	35
	Good relationship with manufacturer	V	36
	Ease of reconstitution	V	37
	Speed of reconstitution	V	38
	Ease of administration	V	39
	Cost	V	40
Q11	How satisfied are you with the currently available recombinant Factor VIII products? Would you say you were		
	SHOW CARD 1		41
	Very dissatisfied		1
	Fairly dissatisfied		2
	Neither satisfied nor dissatisfied		3
	Fairly satisfied		4
	Very satisfied		5
	Don't know		V

No	Question / Answer	Code	Skip to
Q12	What improvements would you like to see made to recombinant Factor VIII products?		
	<b>PROBE FULLY</b>	(42)	
	Reduced use of albumin/protein	1	
	Improved efficacy/response	2	
	Longer lasting effect/longer half-life	3	
	Improved speed of response/effect	4	
	Improved safety (unspecified)	5	
	Fewer adverse reactions	6	
	Reduced/no albumin reaction	7	
	Reduced/no (viral) contamination	8	
	Reduced immunity/resistance/inhibitor development	9	
	Higher potencies/large vial sizes	0	
		(43)	
	Reduced volume of diluent/infusion	1	
	Indication for continuous infusion	2	
	Improved storage (refrigeration not required)	3	
	Longer shelf-life	4	
	Improved supply/availability	5	
	Clearer storage instructions	6	
	Improved packaging/less wastage of ancillary products	7	
	Improved/easier reconstitution	8	
	Faster reconstitution	9	
	Improved/easier administration	0	
	Reduced cost	X	
		(44)	
		(45)	
		(46)	
		(47)	
	Other (please specify)	X	
	.....		
	.....		
	Don't know	V	

No	Question / Answer	Code	Score
	<p><b>HAND NURSE SHOW CARD A</b></p> <p>THIS CARD LISTS SEVERAL FEATURES ON WHICH POTENTIAL NEW RECOMBINANT PRODUCTS FOR HAEMOPHILIA A MIGHT DIFFER PLEASE TAKE A FEW MINUTES TO READ OVER THE FEATURES AND THEIR VARIOUS LEVELS, AS THIS INFORMATION WILL MAKE THE FOLLOWING EXERCISE RUN MORE SMOOTHLY</p> <p><b>ALLOW TIME TO READ ALL INFORMATION ON THE CARD</b></p> <p>I HAVE HERE 32 CARDS, EACH DESCRIBING A POTENTIAL RECOMBINANT FACTOR VIII PRODUCT WITH A UNIQUE COMBINATION OF FEATURES NO TWO CARDS ARE EXACTLY THE SAME FOR THE PURPOSE OF THIS EXERCISE, PLEASE IMAGINE THAT THESE 32 POTENTIAL PRODUCTS ARE THE ONLY ONES AVAILABLE FOR THE TREATMENT OF HAEMOPHILIA A</p> <p><b>HAND NURSE SHUFFLED CARDS</b></p> <p>CONSIDERING YOUR PATIENTS WITH HAEMOPHILIA A, PLEASE SORT THESE 32 POTENTIAL PRODUCTS INTO <u>3 PILES</u> ACCORDING TO YOUR INTEREST IN USING THEM ONE PILE SHOULD CONTAIN THOSE PRODUCTS THAT YOU WOULD BE <u>MOST</u> INTERESTED IN USING, ONE THOSE PRODUCTS THAT YOU <u>MIGHT</u> CONSIDER USING AND ONE THOSE PRODUCTS THAT YOU WOULD BE <u>LEAST</u> INTERESTED IN USING YOU CAN HAVE ANY NUMBER OF CARDS IN EACH OF THE 3 PILES</p> <p><b>ASSUME THESE PRODUCTS ARE EQUAL ON ANY FEATURES THAT ARE NOT INCLUDED ON THE CARDS</b></p> <p>THIS IS A VERY IMPORTANT PART OF THE STUDY PLEASE TAKE YOUR TIME AS WE REALISE THIS TASK REQUIRES CAREFUL CONSIDERATION</p> <p><b>WAIT UNTIL THE NURSE HAS SORTED ALL THE CARDS INTO THREE PILES THEN CONTINUE</b></p> <p>I WOULD NOW LIKE YOU TO RANK THESE 32 CARDS FROM TOP TO BOTTOM STARTING WITH THE PRODUCT YOU ARE MOST INTERESTED IN USING FOR HAEMOPHILIA ON THE TOP, THROUGH TO THE PRODUCT YOU ARE LEAST INTERESTED IN USING ON THE BOTTOM</p> <p>PLEASE BEGIN BY RANKING THESE PRODUCTS IN THE "MOST INTERESTED" PILE</p> <p>AFTER "MOST INTERESTED" PILE IS RANKED, ASK THE NURSE TO CONTINUE WITH THE PILE OF PRODUCTS HE/SHE "MIGHT USE" AND THEN FINALLY RANK THE "LEAST INTERESTED" PILE</p> <p><b>ONCE THE NURSE HAS FINISHED SAY</b></p> <p>PLEASE READ OUT THE NUMBERS OF THE CARDS IN THE ORDER YOU HAVE ARRANGED THEM THE FIRST NUMBER YOU READ OUT SHOULD BE THE PRODUCT YOU ARE <u>MOST</u> INTERESTED IN USING AND THE LAST NUMBER YOU READ OUT SHOULD BE THE PRODUCT YOU ARE <u>LEAST</u> INTERESTED IN USING</p> <p><b>RECORD RESPONSES ON NEXT PAGE</b></p>		

		(1)-(2)	(3)-(11)
		13	REPEAT
<b>WRITE IN EACH NUMBER IN THE APPROPRIATE COLUMN BELOW</b>			
RANK	PRODUCT CARD NUMBER	RANK	PRODUCT CARD NUMBER
1 (MOST LIKELY)	(12) (13)	17	(44) (45)
	(14) (15)	18	(46) (47)
2	(16) (17)	19	(48) (49)
3	(18) (19)	20	(50) (51)
4	(20) (21)	21	(52) (53)
5	(22) (23)	22	(54) (55)
6	(24) (25)	23	(56) (57)
7	(26) (27)	24	(58) (59)
8	(28) (29)	25	(60) (61)
9	(30) (31)	26	(62) (63)
10	(32) (33)	27	(64) (65)
11	(34) (35)	28	(66) (67)
12	(36) (37)	29	(68) (69)
13	(38) (39)	30	(70) (71)
14	(40) (41)	31	(72) (73)
15	(42) (43)	32 (LEAST LIKELY)	(74) (75)
16			

No.	Question / Answer	Ccra	Scrr
Q13	Considering the potential product that you ranked as the one you would be most interested in using, what are your reasons for ranking it first? <b>PROBE FULLY</b>		
		(76)	
		(77)	
		(78)	
Q14	Considering the potential product that you ranked as the one you would be most likely to use, how interested would you be in using it in the haemophilia A patients treated at this centre? Would you say you were <b>SHOW CARD 2</b>		
		(79)	
	Not at all interested	1	
	Not very interested	2	
	Neither interested nor disinterested	3	
	Fairly interested	4	
	Very interested	5	
	Don't know	V	

THANK AND CLOSE

Version 3 (Final)  
23<sup>rd</sup> November 1999

09	0398	8		2
CC	V No	USA	Serial	Nur

J. RECKNER ASSOCIATES - 99-1531

# RECOMBINANT FACTOR VIII POSITIONING STUDY NURSE QUESTIONNAIRE - USA

NAME \_\_\_\_\_ (PRINT)

CENTRE NAME \_\_\_\_\_ (PRINT)

ADDRESS \_\_\_\_\_ (PRINT)

\_\_\_\_\_

\_\_\_\_\_

POST CODE \_\_\_\_\_ (PRINT)

TEL NO \_\_\_\_\_

## YEAR OF QUALIFICATION

(12) (13)

1	9		
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## TYPE OF HOSPITAL

(15)

Private for profit 1

Private not for profit 2

(16)

## REGIONS

(14)

CT,ME,MA,NH,VT,RI 1

NJ,NY,PA 2

IL,IN,MI,OH,WI 3

IA,KS,MN,MO,NE,ND,SD 4

DE,DC,FL,GA,MD,NC,SC,VA,WV 5

AL,KY,MS,TN 6

AR,LA,OK,TX 7

AZ,CO,ID,MT,NV,NM,UT,WY 8

CA,OR,WA 9

Teaching 1

Non teaching 2

## HOSPITAL BED SIZE

(17) (18) (19) (20)

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(21)

Don't know V

## COLUMNS (22)-(64) BLANK

TIME STARTED \_\_\_\_\_ DATE OF INTERVIEW (65) (66) (67) (68) (69) (70) (71) (72) (73) (74)

TIME FINISHED \_\_\_\_\_ INTERVIEWED BY (75) (76) (77) (78) (79)

OUO (80) 1 2 3 4 5 6 7 8 9 O X V

RESPONDENT SIGNATURE FOR FEE

INTERVIEWER SIGNATURE

(signature) (signature)

THIS INTERVIEW HAS BEEN CONDUCTED WITHIN THE TERMS OUTLINE D BY THE MRS CODE OF CONDUCT

No	Question / Answer	Code	S r c
Q1	<p>Approximately how many haemophilia patients in total are treated at this centre?</p> <p>(12) (13) (14)</p> <p><input type="text"/> <input type="text"/> <input type="text"/></p> <p>Don't know</p>	<p>(1)-(2)</p> <p>10</p> <p>3--</p> <p>PEPE--</p> <p>15</p> <p>V</p>	
Q2	<p>Of all haemophilia patients treated at this centre, what percentage have haemophilia A and what percentage have haemophilia B?</p> <p>i) Haemophilia A</p> <p>(16) (17) (18)</p> <p><input type="text"/> <input type="text"/> <input type="text"/> %</p> <p>Don't know</p> <p>ii) Haemophilia B</p> <p>(20) (21) (22)</p> <p><input type="text"/> <input type="text"/> <input type="text"/> %</p> <p>None</p> <p>Don't know</p> <p><b>RESPONDENT MUST HAVE HAEMOPHILIA A PATIENTS (SEE SCREENER)</b> <b>ENSURE TOTAL EQUALS 100%</b></p>	<p>( 3)</p> <p>V</p> <p>(23)</p> <p>O</p> <p>V</p>	
	<p><b>EXPLAIN TO THE RESPONDENT THAT THE REST OF THE QUESTIONNAIRE CONCENTRATES EXCLUSIVELY ON HAEMOPHILIA A</b></p>		
Q3	<p>Thinking of all the haemophilia A patients treated at this centre, what percentage are adults and what percentage are paediatrics?</p> <p>i) Adults</p> <p>(24) (25) (26)</p> <p><input type="text"/> <input type="text"/> <input type="text"/> %</p> <p>None</p> <p>Don't know</p> <p>ii) Paediatrics</p> <p>(28) (29) (30)</p> <p><input type="text"/> <input type="text"/> <input type="text"/> %</p> <p>None</p> <p>Don't know</p> <p><b>ENSURE TOTAL EQUALS 100%</b></p>	<p>(27)</p> <p>O</p> <p>V</p> <p>(31)</p> <p>O</p> <p>V</p>	



No	Question / Answer	Code	Skip to
Q4	<p>Thinking of all the haemophilia A patients treated at this centre, what percentage are mild, what percentage are moderate and what percentage are severe?</p> <p>i) Mild</p> <div style="display: flex; align-items: center;"> <div style="text-align: center;"> (32)  <input type="text"/> </div> <div style="text-align: center;"> (33)  <input type="text"/> </div> <div style="text-align: center;"> (34)  <input type="text"/> </div> <div style="margin-left: 10px;">%</div> </div> <div style="display: flex; justify-content: flex-end; margin-top: 5px;"> None Don't know </div> <p>ii) Moderate</p> <div style="display: flex; align-items: center;"> <div style="text-align: center;"> (36)  <input type="text"/> </div> <div style="text-align: center;"> (37)  <input type="text"/> </div> <div style="text-align: center;"> (38)  <input type="text"/> </div> <div style="margin-left: 10px;">%</div> </div> <div style="display: flex; justify-content: flex-end; margin-top: 5px;"> None Don't know </div> <p>iii) Severe</p> <div style="display: flex; align-items: center;"> <div style="text-align: center;"> (40)  <input type="text"/> </div> <div style="text-align: center;"> (41)  <input type="text"/> </div> <div style="text-align: center;"> (42)  <input type="text"/> </div> <div style="margin-left: 10px;">%</div> </div> <div style="display: flex; justify-content: flex-end; margin-top: 5px;"> None Don't know </div> <p><b>ENSURE TOTAL EQUALS 100%</b></p>	(35) O V  (39) O V  (43) O V	
Q5	<p>Thinking of all the haemophilia A patients treated at this centre, what percentage currently use recombinant Factor VIII products and what percentage use human plasma derived Factor VIII products?</p> <p>i) Recombinant</p> <div style="display: flex; align-items: center;"> <div style="text-align: center;"> (44)  <input type="text"/> </div> <div style="text-align: center;"> (45)  <input type="text"/> </div> <div style="text-align: center;"> (46)  <input type="text"/> </div> <div style="margin-left: 10px;">%</div> </div> <div style="display: flex; justify-content: flex-end; margin-top: 5px;">Don't know</div> <p>ii) Human plasma</p> <div style="display: flex; align-items: center;"> <div style="text-align: center;"> (48)  <input type="text"/> </div> <div style="text-align: center;"> (49)  <input type="text"/> </div> <div style="text-align: center;"> (50)  <input type="text"/> </div> <div style="margin-left: 10px;">%</div> </div> <div style="display: flex; justify-content: flex-end; margin-top: 5px;"> None Don't know </div> <p><b>RESPONDENT MUST HAVE PATIENTS ON RECOMBINANT PRODUCTS (SEE SCREENER)</b>  <b>ENSURE TOTAL EQUALS 100%</b></p>	(47) V  (51) O V	
Q6	<p>Approximately how many haemophilia A patients do you see in a typical week?</p> <div style="display: flex; align-items: center;"> <div style="text-align: center;"> (52)  <input type="text"/> </div> <div style="text-align: center;"> (53)  <input type="text"/> </div> <div style="text-align: center;"> (54)  <input type="text"/> </div> </div> <div style="display: flex; justify-content: flex-end; margin-top: 5px;">Don't know</div>	(55) V	
Q7	<p>Typically on how many occasions per week do you reconstitute/administer <u>recombinant</u> Factor VIII products?</p> <div style="display: flex; align-items: center;"> <div style="text-align: center;"> (56)  <input type="text"/> </div> <div style="text-align: center;"> (57)  <input type="text"/> </div> <div style="text-align: center;"> (58)  <input type="text"/> </div> <div style="margin-left: 10px;">occasions <u>per week</u></div> </div> <div style="display: flex; justify-content: flex-end; margin-top: 5px;">Don't know</div> <p><b>RESPONDENT MUST BE INVOLVED IN THE RECONSTITUTION/ADMINISTRATION OF RECOMBINANT PRODUCTS (SEE SCREENER)</b></p>	(59) V	

No	Question / Answer	Code	Score																																																																
Q8a	Which specific brands of Factor VIII products are currently used in patients at this centre (both recombinant and human plasma derived products)?																																																																		
Q8b	What percentage of the patients currently use ( product from Q8a ) ASK FOR EACH BRAND NAMED AT Q8a ENSURE TOTAL EQUALS 100%																																																																		
	<table border="0"> <thead> <tr> <th></th> <th>Q8a Usage</th> <th>Q8b Percentage of patients</th> <th></th> </tr> </thead> <tbody> <tr> <td><u>Recombinant</u></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Bioclone</td> <td>(12) 1</td> <td>(17) (18) (19) % [ ] [ ] [ ] Don't know</td> <td>20</td> </tr> <tr> <td>Helixate</td> <td>2</td> <td>(21) (22) (23) % [ ] [ ] [ ] Don't know</td> <td>24</td> </tr> <tr> <td>Kogenate</td> <td>3</td> <td>(25) (26) (27) % [ ] [ ] [ ] Don't know</td> <td>(26)</td> </tr> <tr> <td>Recombinant</td> <td>4</td> <td>(29) (30) (31) % [ ] [ ] [ ] Don't know</td> <td>32</td> </tr> <tr> <td>Refacto</td> <td>5</td> <td>(33) (34) (35) % [ ] [ ] [ ] Don't know</td> <td>33</td> </tr> <tr> <td><u>Human plasma</u></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Alphanate</td> <td>(13) 1</td> <td>(37) (38) (39) % [ ] [ ] [ ] Don't know</td> <td>40</td> </tr> <tr> <td>Humate-P</td> <td>7</td> <td>(49) (50) (51) % [ ] [ ] [ ] Don't know</td> <td>52</td> </tr> <tr> <td>Hemofil M</td> <td>9</td> <td>(53) (54) (55) % [ ] [ ] [ ] Don't know</td> <td>53</td> </tr> <tr> <td>Koate DVI</td> <td>V</td> <td>(57) (58) (59) % [ ] [ ] [ ] Don't know</td> <td>(60)</td> </tr> <tr> <td>Monarc M</td> <td>(14) 2</td> <td>(61) (62) (63) % [ ] [ ] [ ] Don't know</td> <td>64</td> </tr> <tr> <td>Monoclone-P</td> <td>3</td> <td>(65) (66) (67) % [ ] [ ] [ ] Don't know</td> <td>(68)</td> </tr> <tr> <td>Other (specify)</td> <td>(15) X</td> <td>(69) (70) (71) % [ ] [ ] [ ] Don't know</td> <td>(72)</td> </tr> <tr> <td></td> <td>(16) X</td> <td>(73) (74) (75) % [ ] [ ] [ ] Don't know</td> <td>(76)</td> </tr> </tbody> </table>		Q8a Usage	Q8b Percentage of patients		<u>Recombinant</u>				Bioclone	(12) 1	(17) (18) (19) % [ ] [ ] [ ] Don't know	20	Helixate	2	(21) (22) (23) % [ ] [ ] [ ] Don't know	24	Kogenate	3	(25) (26) (27) % [ ] [ ] [ ] Don't know	(26)	Recombinant	4	(29) (30) (31) % [ ] [ ] [ ] Don't know	32	Refacto	5	(33) (34) (35) % [ ] [ ] [ ] Don't know	33	<u>Human plasma</u>				Alphanate	(13) 1	(37) (38) (39) % [ ] [ ] [ ] Don't know	40	Humate-P	7	(49) (50) (51) % [ ] [ ] [ ] Don't know	52	Hemofil M	9	(53) (54) (55) % [ ] [ ] [ ] Don't know	53	Koate DVI	V	(57) (58) (59) % [ ] [ ] [ ] Don't know	(60)	Monarc M	(14) 2	(61) (62) (63) % [ ] [ ] [ ] Don't know	64	Monoclone-P	3	(65) (66) (67) % [ ] [ ] [ ] Don't know	(68)	Other (specify)	(15) X	(69) (70) (71) % [ ] [ ] [ ] Don't know	(72)		(16) X	(73) (74) (75) % [ ] [ ] [ ] Don't know	(76)		
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No	Question / Answer	(1)-(2) 12	(3)-(11) REPEAT
		Code	Skip to
Q9	What factors influence the choice of Factor VIII treatment for haemophilia A patients?		
	<b>PROBE FULLY</b>	(12)	
	Recombinant vs human plasma-derived	1	
	Well-established/standard product	2	
	Albumin/protein content	3	
	Efficacy/response rates	4	
	Duration of effect/half life	5	
	Speed of response/effect	6	
	Safety (Unspecified)	7	
	Lack of adverse reactions	8	
	Lack of albumin reaction	9	
	Lack of (viral) contamination	0	
	Lack of immunity/resistance/lack of inhibitor development	X	
	Range of potencies/vial sizes	V	
		(13)	
	Diluent/infusion volume	1	
	Storage (refrigeration vs room temperature)	2	
	Shelf-life	3	
	Supply/availability	4	
	Delivery to patient's home	5	
	Manufacturer (e.g. reputation/involvement in haemophilia)	6	
	(Good) relationship with the manufacturer	7	
	Ease of reconstitution	8	
	Speed of reconstitution	9	
	Ease of administration	0	
	Cost	X	
		(14)	
		(15)	
		(16)	
		(17)	
	Other (please specify)	X	
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	Don't know	V	

No	Question / Answer	Code	Sub																																																																																																																																																																																																																																																																																																																
Q10	How important are the following factors in the choice of Factor VIII treatment for haemophilia A patients? Please use a 10 point rating scale where 1 equals "not at all important" and 10 equals "extremely important"																																																																																																																																																																																																																																																																																																																		
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<td>Speed of response/effect</td> <td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td><td>10</td> <td>V</td> <td>23</td> </tr> <tr> <td>Safety (unspecified)</td> <td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td><td>10</td> <td>/</td> <td>24</td> </tr> <tr> <td>Lack of adverse reactions</td> <td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td><td>10</td> <td>C</td> <td>25</td> </tr> <tr> <td>Lack of albumin reaction</td> <td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td><td>10</td> <td>V</td> <td>26</td> </tr> <tr> <td>Lack of (viral) contamination</td> <td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td><td>10</td> <td>V</td> <td>27</td> </tr> <tr> <td>Lack of immunity/resistance/inhibitor development</td> 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sizes	1	2	3	4	5	6	7	8	9	10	V	29	Diluent/infusion volume	1	2	3	4	5	6	7	8	9	10	/	30	Storage (refrigeration vs room temperature)	1	2	3	4	5	6	7	8	9	10	V	C	Shelf-life	1	2	3	4	5	6	7	8	9	10	/	32	Supply/availability	1	2	3	4	5	6	7	8	9	10	V	33	Delivery to patient's home	1	2	3	4	5	6	7	8	9	10	V	34	Manufacturer (i.e. reputation/involvement in haemophilia)	1	2	3	4	5	6	7	8	9	10	V	35	Good relationship with manufacturer	1	2	3	4	5	6	7	8	9	10	C	36	Ease of reconstitution	1	2	3	4	5	6	7	8	9	10	V	37	Speed of reconstitution	1	2	3	4	5	6	7	8	9	10	V	38	Ease of administration	1	2	3	4	5	6	7	8	9	10	V	39	Cost	1	2	3	4	5	6	7	8	9	10	V	40		
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Q11	How satisfied are you with the currently available recombinant Factor VIII products? Would you say you were																																																																																																																																																																																																																																																																																																																		
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	Fairly dissatisfied	2																																																																																																																																																																																																																																																																																																																	
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	Fairly satisfied	4																																																																																																																																																																																																																																																																																																																	
	Very satisfied	5																																																																																																																																																																																																																																																																																																																	
	Don't know																																																																																																																																																																																																																																																																																																																		

No	Question / Answer	Code	Skip to
Q12	What improvements would you like to see made to recombinant Factor VIII products?		
	<b>PROBE FULLY</b>	(42)	
	Reduced use of albumin/protein	1	
	Improved efficacy/response	2	
	Longer lasting effect/longer half-life	3	
	Improved speed of response/effect	4	
	Improved safety (unspecified)	5	
	Fewer adverse reactions	6	
	Reduced/no albumin reaction	7	
	Reduced/no (viral) contamination	8	
	Reduced immunity/resistance/inhibitor development	9	
	Higher potencies/large vial sizes	0	
		(43)	
	Reduced volume of diluent/infusion	1	
	Indication for continuous infusion	2	
	Improved storage (refrigeration not required)	3	
	Longer shelf-life	4	
	Improved supply/availability	5	
	Clearer storage instructions	6	
	Improved packaging/less wastage of ancillary products	7	
	Improved/easier reconstitution	8	
	Faster reconstitution	9	
	Improved/easier administration	0	
	Reduced cost	X	
		(44)	
		(45)	
		(46)	
		(47)	
	Other (please specify)	X	
	-----		
	-----		
	Don't know	V	

No	Question / Answer	Code	Sect :
	<p><b>HAND NURSE SHOW CARD A</b></p> <p>THIS CARD LISTS SEVERAL FEATURES ON WHICH POTENTIAL NEW RECOMBINANT PRODUCTS FOR HAEMOPHILIA A MIGHT DIFFER PLEASE TAKE A FEW MINUTES TO READ OVER THE FEATURES AND THEIR VARIOUS LEVELS, AS THIS INFORMATION WILL MAKE THE FOLLOWING EXERCISE RUN MORE SMOOTHLY</p> <p><b>ALLOW TIME TO READ ALL INFORMATION ON THE CARD</b></p> <p>I HAVE HERE 32 CARDS, EACH DESCRIBING A POTENTIAL RECOMB NANT FACTOR VIII PRODUCT WITH A UNIQUE COMBINATION OF FEATURES NO TWO CARDS ARE EXACTLY THE SAME FOR THE PURPOSE OF THIS EXERCISE, PLEASE IMAGINE THAT THESE 32 POTENTIAL PRODUCTS ARE THE ONLY ONES AVAILABLE FOR THE TREATMENT OF HAEMOPHILIA A</p> <p><b>HAND NURSE SHUFFLED CARDS</b></p> <p>CONSIDERING YOUR PATIENTS WITH HAEMOPHILIA A, PLEASE SORT THESE 32 POTENTIAL PRODUCTS INTO <u>3 PILES</u> ACCORDING TO YOUR INTEREST IN USING THEM ONE PILE SHOULD CONTAIN THOSE PRODUCTS THAT YOU WOULD BE <u>MOST</u> INTERESTED IN USING, ONE THOSE PRODUCTS THAT YOU <u>MIGHT</u> CONSIDER USING AND ONE THOSE PRODUCTS THAT YOU WOULD BE <u>LEAST</u> INTERESTED IN USING YOU CAN HAVE ANY NUMBER OF CARDS IN EACH OF THE 3 PILES</p> <p>ASSUME THESE PRODUCTS ARE EQUAL ON ANY FEATURES THAT ARE NOT INCLUDED ON THE CARDS</p> <p>THIS IS A VERY IMPORTANT PART OF THE STUDY PLEASE TAKE YOUR TIME AS WE REALISE THIS TASK REQUIRES CAREFUL CONSIDERATION</p> <p><b>WAIT UNTIL THE NURSE HAS SORTED ALL THE CARDS INTO THREE PILES, THEN CONTINUE</b></p> <p>I WOULD NOW LIKE YOU TO RANK THESE 32 CARDS FROM TOP TO BOTTOM, STARTING WITH THE PRODUCT YOU ARE MOST INTERESTED IN USING FOR HAEMOPHILIA ON THE TOP, THROUGH TO THE PRODUCT YOU ARE LEAST INTERESTED IN USING ON THE BOTTOM</p> <p>PLEASE BEGIN BY RANKING THESE PRODUCTS IN THE "MOST INTERESTED" PILE</p> <p>AFTER "MOST INTERESTED" PILE IS RANKED, ASK THE NURSE TO CONTINUE WITH THE PILE OF PRODUCTS HE/SHE "MIGHT USE" AND THEN FINALLY RANK THE "LEAST INTERESTED" PILE</p> <p><b>ONCE THE NURSE HAS FINISHED SAY.</b></p> <p>PLEASE READ OUT THE NUMBERS OF THE CARDS IN THE ORDER YOU HAVE ARRANGED THEM THE FIRST NUMBER YOU READ OUT SHOULD BE THE PRODUCT YOU ARE <u>MOST</u> INTERESTED IN USING AND THE LAST NUMBER YOU READ OUT SHOULD BE THE PRODUCT YOU ARE <u>LEAST</u> INTERESTED IN USING</p> <p><b>RECORD RESPONSES ON NEXT PAGE</b></p>		

		(1)-(2)	(3)-(11)
		13	REPEAT
<b>WRITE IN EACH NUMBER IN THE APPROPRIATE COLUMN BELOW</b>			
RANK	PRODUCT CARD NUMBER	RANK	PRODUCT CARD NUMBER
	(12) (13)		(44) (45)
1 (MOST LIKELY)	<input type="text"/> <input type="text"/>	17	<input type="text"/> <input type="text"/>
	(14) (15)		(46) (47)
2	<input type="text"/> <input type="text"/>	18	<input type="text"/> <input type="text"/>
	(16) (17)		(48) (49)
3	<input type="text"/> <input type="text"/>	19	<input type="text"/> <input type="text"/>
	(18) (19)		(50) (51)
4	<input type="text"/> <input type="text"/>	20	<input type="text"/> <input type="text"/>
	(20) (21)		(52) (53)
5	<input type="text"/> <input type="text"/>	21	<input type="text"/> <input type="text"/>
	(22) (23)		(54) (55)
6	<input type="text"/> <input type="text"/>	22	<input type="text"/> <input type="text"/>
	(24) (25)		(56) (57)
7	<input type="text"/> <input type="text"/>	23	<input type="text"/> <input type="text"/>
	(26) (27)		(58) (59)
8	<input type="text"/> <input type="text"/>	24	<input type="text"/> <input type="text"/>
	(28) (29)		(60) (61)
9	<input type="text"/> <input type="text"/>	25	<input type="text"/> <input type="text"/>
	(30) (31)		(62) (63)
10	<input type="text"/> <input type="text"/>	26	<input type="text"/> <input type="text"/>
	(32) (33)		(64) (65)
11	<input type="text"/> <input type="text"/>	27	<input type="text"/> <input type="text"/>
	(34) (35)		(66) (67)
12	<input type="text"/> <input type="text"/>	28	<input type="text"/> <input type="text"/>
	(36) (37)		(68) (69)
13	<input type="text"/> <input type="text"/>	29	<input type="text"/> <input type="text"/>
	(38) (39)		(70) (71)
14	<input type="text"/> <input type="text"/>	30	<input type="text"/> <input type="text"/>
	(40) (41)		(72) (73)
15	<input type="text"/> <input type="text"/>	31	<input type="text"/> <input type="text"/>
	(42) (43)		(74) (75)
16	<input type="text"/> <input type="text"/>	32 (LEAST LIKELY)	<input type="text"/> <input type="text"/>

No	Question / Answer	Code	Score
Q13	Considering the potential product that you ranked as the one you would be most interested in using, what are your reasons for ranking it first? <b>PROBE FULLY</b>		
		176	
		177	
		178	
Q14	Considering the potential product that you ranked as the one you would be most likely to use, how interested would you be in using it in the haemophilia A patients treated at this centre? Would you say you were <b>SHOW CARD 2</b>		
		179	
	Not at all interested	1	
	Not very interested	2	
	Neither interested nor disinterested	3	
	Fairly interested	4	
	Very interested	5	
	Don't know	6	



		(1)-(2)	(3)-(11)
		18	REPEAT
No	Question / Answer	Code	Skip to
Q15	<p>Considering the potential product that you ranked as the one you would be most likely to use, would you be willing to advocate paying a price premium for that product?</p> <p style="text-align: right;">Yes -----</p> <p style="text-align: right;">No -----</p> <p style="text-align: right;">Don't know -----</p>	<p>(12)</p> <p>1</p> <p>2</p> <p>V</p>	<p>Q16</p> <p>THANK AND CLOSE</p>
Q16	<p>What percentage price increase over currently available recombinant products would you consider to be acceptable?</p> <p style="text-align: center;">           (13)    (14)    (15)  <input type="text"/> <input type="text"/> <input type="text"/> %            enter percentage         </p> <p style="text-align: right;">Depends -----</p> <p style="text-align: right;">Don't know -----</p> <p>GO TO Q17 IF 'DEPENDS', OTHERWISE THANK AND CLOSE</p>	<p>(16)</p> <p>X</p> <p>V</p>	<p>Q17</p> <p>THANK AND CLOSE</p>
Q17	<p>On what would the acceptable level of price increase depend?</p> <p>PROBE FULLY</p> <p>-----</p> <p>-----</p> <p>-----</p> <p>-----</p> <p>-----</p> <p>-----</p>	<p>(17)</p> <p>(18)</p> <p>(19)</p>	
THANK AND CLOSE			

Version 3 (Final)  
23<sup>rd</sup> November 1999

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INTERNATIONAL HEALTH SURVEYS, LUDGATE HOUSE, 245 BLACKFRIARS ROAD, LONDON SE1 9UL

RECOMBINANT FACTOR VIII POSITIONING STUDY  
NURSE QUESTIONNAIRE -- JAPAN

NAME (PRINT)  
CENTRE NAME (PRINT)  
ADDRESS (PRINT)  
POST CODE (PRINT)  
TEL NO

YEAR OF QUALIFICATION

(12)	(13)
1	9

TYPE OF HOSPITAL (15)

Public 1  
Private 2  
(16)

REGION (14)  
Tokyo 1  
Osaka 2

Teaching 1  
Non-teaching 2

HOSPITAL BED SIZE

(17)	(18)	(19)	(20)

(21)  
Don't know V

COLUMNS (22)-(64) BLANK

TIME STARTED	DATE OF INTERVIEW	(65) (66)	(67) (68)	(69) (70)	(71) (72)	(73) (74)								
				9 9										
TIME FINISHED	INTERVIEWED BY	(75) (76) (77) (78) (79)												
		OUO (80)	1	2	3	4	5	6	7	8	9	O	X	V

RESPONDENT SIGNATURE FOR FEE

INTERVIEWER SIGNATURE

(signature) (signature)  
THIS INTERVIEW HAS BEEN CONDUCTED WITHIN THE TERMS OUTLINED BY THE MRS CODE OF CONDUCT

No	Question / Answer	Code	Score
Q1	Approximately how many haemophilia patients in total are treated at this centre?  <div style="display: flex; justify-content: center; gap: 10px;"> <span>(12)</span> <span>(13)</span> <span>(14)</span> </div> <div style="display: flex; justify-content: center; gap: 10px;"> <input type="text"/> <input type="text"/> <input type="text"/> </div> <div style="text-align: right;">Don't know</div>	151 ✓	
Q2	Of all haemophilia patients treated at this centre, what percentage have haemophilia A and what percentage have haemophilia B?  i) Haemophilia A <div style="display: flex; justify-content: center; gap: 10px;"> <span>(16)</span> <span>(17)</span> <span>(18)</span> </div> <div style="display: flex; justify-content: center; gap: 10px;"> <input type="text"/> <input type="text"/> <input type="text"/> </div> <div style="text-align: right;">Don't know</div> ii) Haemophilia B <div style="display: flex; justify-content: center; gap: 10px;"> <span>(20)</span> <span>(21)</span> <span>(22)</span> </div> <div style="display: flex; justify-content: center; gap: 10px;"> <input type="text"/> <input type="text"/> <input type="text"/> </div> <div style="text-align: right;">None Don't know</div> <b>RESPONDENT MUST HAVE HAEMOPHILIA A PATIENTS (SEE  SCREENER)  ENSURE TOTAL EQUALS 100%</b>	191 ✓  23 ○ ✓	
<b>EXPLAIN TO THE RESPONDENT THAT THE REST OF THE QUESTIONNAIRE CONCENTRATES EXCLUSIVELY ON HAEMOPHILIA A</b>			
Q3	Thinking of all the haemophilia A patients treated at this centre, what percentage are adults and what percentage are paediatrics?  i) Adults <div style="display: flex; justify-content: center; gap: 10px;"> <span>(24)</span> <span>(25)</span> <span>(26)</span> </div> <div style="display: flex; justify-content: center; gap: 10px;"> <input type="text"/> <input type="text"/> <input type="text"/> </div> <div style="text-align: right;">None Don't know</div> ii) Paediatrics <div style="display: flex; justify-content: center; gap: 10px;"> <span>(28)</span> <span>(29)</span> <span>(30)</span> </div> <div style="display: flex; justify-content: center; gap: 10px;"> <input type="text"/> <input type="text"/> <input type="text"/> </div> <div style="text-align: right;">None Don't know</div> <b>ENSURE TOTAL EQUALS 100%</b>	(27) ○ ✓  31 ○ ✓	

No	Question / Answer	Code	Skip to
Q4	<p>Thinking of all the haemophilia A patients treated at this centre, what percentage are mild, what percentage are moderate and what percentage are severe?</p> <p>i) Mild</p> <p>(32) (33) (34)</p> <p><input type="text"/> <input type="text"/> <input type="text"/> %</p> <p>None <input type="radio"/> (35)</p> <p>Don't know <input type="radio"/> V</p> <p>ii) Moderate</p> <p>(36) (37) (38)</p> <p><input type="text"/> <input type="text"/> <input type="text"/> %</p> <p>None <input type="radio"/> (39)</p> <p>Don't know <input type="radio"/> V</p> <p>iii) Severe</p> <p>(40) (41) (42)</p> <p><input type="text"/> <input type="text"/> <input type="text"/> %</p> <p>None <input type="radio"/> (43)</p> <p>Don't know <input type="radio"/> V</p> <p><b>ENSURE TOTAL EQUALS 100%</b></p>		
Q5	<p>Thinking of all the haemophilia A patients treated at this centre, what percentage currently use recombinant Factor VIII products and what percentage use human plasma derived Factor VIII products?</p> <p>i) Recombinant</p> <p>(44) (45) (46)</p> <p><input type="text"/> <input type="text"/> <input type="text"/> %</p> <p>Don't know <input type="radio"/> (47)</p> <p>ii) Human plasma</p> <p>(48) (49) (50)</p> <p><input type="text"/> <input type="text"/> <input type="text"/> %</p> <p>None <input type="radio"/> (51)</p> <p>Don't know <input type="radio"/> V</p> <p><b>RESPONDENT MUST HAVE PATIENTS ON RECOMBINANT PRODUCTS (SEE SCREENER)</b></p> <p><b>ENSURE TOTAL EQUALS 100%</b></p>		
Q6	<p>Approximately how many haemophilia A patients do you see in a typical week?</p> <p>(52) (53) (54)</p> <p><input type="text"/> <input type="text"/> <input type="text"/></p> <p>Don't know <input type="radio"/> (55)</p> <p><input type="radio"/> V</p>		
Q7	<p>Typically on how many occasions per week do you reconstitute/administer <u>recombinant</u> Factor VIII products?</p> <p>(56) (57) (58)</p> <p><input type="text"/> <input type="text"/> <input type="text"/> occasions <u>per week</u></p> <p>Don't know <input type="radio"/> (59)</p> <p><input type="radio"/> V</p> <p><b>RESPONDENT MUST BE INVOLVED IN THE RECONSTITUTION/ADMINISTRATION OF RECOMBINANT PRODUCTS (SEE SCREENER)</b></p>		

No	Question / Answer	Code	Score
Q8a	Which specific brands of Factor VIII products are currently used in patients at this centre (both recombinant and human plasma derived products)?		
Q8b	What percentage of the patients currently use ( product from Q8a ) ASK FOR EACH BRAND NAMED AT Q8a ENSURE TOTAL EQUALS 100%		
	Q8a Usage	Q8b Percentage of patients	
	<b>Recombinant</b>		
	Kogenate	(12) 3 (25) (26) (27) % 128 Don't know V	
	Recombinant	4 (29) (30) (31) % 32 Don't know V	
	<b>Human plasma</b>		
	Contact F	(13) 3 (41) (42) (43) % 41 Don't know V	
	Crosseight M	4 (45) (46) (47) % 48 Don't know V	
	Haemate P	7 (49) (50) (51) % 52 Don't know V	
	Haemofil M	9 (53) (54) (55) % 55 Don't know V	
	COLUMN (14) BLANK		
	Other (specify)	(15) X (69) (70) (71) % 72 Don't know V	
		(16) X (73) (74) (75) % 76 Don't know V	

No	Question / Answer	(1)-(2) 12	(3)-(11) REPEAT
		Code	Skip to
Q9	What factors influence the choice of Factor VIII treatment for haemophilia A patients?		
	<b>PROBE FULLY</b>	(12)	
	Recombinant vs human plasma-derived	1	
	Well-established/standard product	2	
	Albumin/protein content	3	
	Efficacy/response rates	4	
	Duration of effect/half life	5	
	Speed of response/effect	6	
	Safety (unspecified)	7	
	Lack of adverse reactions	8	
	Lack of albumin reaction	9	
	Lack of (viral) contamination	0	
	Lack of immunity/resistance/lack of inhibitor development	X	
	Range of potencies/vial sizes	V	
		(13)	
	Diluent/infusion volume	1	
	Storage (refrigeration vs room temperature)	2	
	Shelf-life	3	
	Supply/availability	4	
	Delivery to patient's home	5	
	Manufacturer (e.g. reputation/involvement in haemophilia)	6	
	(Good) relationship with the manufacturer	7	
	Ease of reconstitution	8	
	Speed of reconstitution	9	
	Ease of administration	0	
	Cost	X	
		(14)	
		(15)	
		(16)	
		(17)	
	Other (please specify)	X	
	-----		
	-----		
	Don't know	V	

No	Question / Answer	Code	Score															
Q10	How important are the following factors in the choice of Factor VIII treatment for haemophilia A patients? Please use a 10 point rating scale where 1 equals "not at all important" and 10 equals "extremely important"																	
	<table border="0"> <tr> <td></td> <td>Not at all important</td> <td>Extremely important</td> <td></td> </tr> <tr> <td></td> <td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td><td>10</td> </tr> </table>		Not at all important	Extremely important			1	2	3	4	5	6	7	8	9	10		
	Not at all important	Extremely important																
	1	2	3	4	5	6	7	8	9	10								
	Recombinant vs human plasma-derived	V	3															
	Well-established/standard product	V	19															
	Albumin/protein content	V	20															
	Efficacy/response rates	V	2															
	Duration of effect/half-life	V	22															
	Speed of response/effect	V	20															
	Safety (unspecified)	V	24															
	Lack of adverse reactions	V	25															
	Lack of albumin reaction	V	25															
	Lack of (viral) contamination	V	27															
	Lack of immunity/resistance/inhibitor development	V	25															
	Range of potencies/vial sizes	V	29															
	Diluent/infusion volume	V	30															
	Storage (refrigeration vs room temperature)	V	3															
	Shelf-life	V	32															
	Supply/availability	V	30															
	Delivery to patient's home	V	34															
	Manufacturer (i.e. reputation/involvement in haemophilia)	V	35															
	Good relationship with manufacturer	V	36															
	Ease of reconstitution	V	37															
	Speed of reconstitution	V	38															
	Ease of administration	V	39															
	Cost	V	40															
Q11	How satisfied are you with the currently available recombinant Factor VIII products? Would you say you were																	
	SHOW CARD 1		(41)															
	Very dissatisfied		1															
	Fairly dissatisfied		2															
	Neither satisfied nor dissatisfied		3															
	Fairly satisfied		4															
	Very satisfied		5															
	Don't know		V															

No	Question / Answer	Code	Skip to
Q12	What improvements would you like to see made to recombinant Factor VIII products?		
	PROBE FULLY	(42)	
	Reduced use of albumin/protein	1	
	Improved efficacy/response	2	
	Longer lasting effect/longer half-life	3	
	Improved speed of response/effect	4	
	Improved safety (unspecified)	5	
	Fewer adverse reactions	6	
	Reduced/no albumin reaction	7	
	Reduced/no (viral) contamination	8	
	Reduced immunity/resistance/inhibitor development	9	
	Higher potencies/larger vial sizes	0	
		(43)	
	Reduced volume of diluent/infusion	1	
	Indication for continuous infusion	2	
	Improved storage (refrigeration not required)	3	
	Longer shelf-life	4	
	Improved supply availability	5	
	Clearer storage instructions	6	
	Improved packaging/less wastage of ancillary products	7	
	Improved/easier reconstitution	8	
	Faster reconstitution	9	
	Improved/easier administration	0	
	Reduced cost	X	
		(44)	
		(45)	
		(46)	
		(47)	
	Other (please specify)	X	
	-----		
	-----		
	Don't know	V	



No	Question / Answer	Code	S
	<p><b>HAND NURSE SHOW CARD A</b></p> <p>THIS CARD LISTS SEVERAL FEATURES ON WHICH POTENTIAL NEW RECOMBINANT PRODUCTS FOR HAEMOPHILIA A MIGHT DIFFER. PLEASE TAKE A FEW MINUTES TO READ OVER THE FEATURES AND THEIR VARIOUS LEVELS, AS THIS INFORMATION WILL MAKE THE FOLLOWING EXERCISE RUN MORE SMOOTHLY</p> <p><b>ALLOW TIME TO READ ALL INFORMATION ON THE CARD</b></p> <p>I HAVE HERE 32 CARDS, EACH DESCRIBING A POTENTIAL RECOMBINANT FACTOR VIII PRODUCT WITH A UNIQUE COMBINATION OF FEATURES. NO TWO CARDS ARE EXACTLY THE SAME. FOR THE PURPOSE OF THIS EXERCISE, PLEASE IMAGINE THAT THESE 32 POTENTIAL PRODUCTS ARE THE ONLY ONES AVAILABLE FOR THE TREATMENT OF HAEMOPHILIA A.</p> <p><b>HAND NURSE SHUFFLED CARDS</b></p> <p>CONSIDERING YOUR PATIENTS WITH HAEMOPHILIA A, PLEASE SORT THESE 32 POTENTIAL PRODUCTS INTO <u>3 PILES</u> ACCORDING TO YOUR INTEREST IN USING THEM. ONE PILE SHOULD CONTAIN THOSE PRODUCTS THAT YOU WOULD BE <u>MOST</u> INTERESTED IN USING, ONE THOSE PRODUCTS THAT YOU <u>MIGHT</u> CONSIDER USING AND ONE THOSE PRODUCTS THAT YOU WOULD BE <u>LEAST</u> INTERESTED IN USING. YOU CAN HAVE ANY NUMBER OF CARDS IN EACH OF THE 3 PILES.</p> <p>ASSUME THESE PRODUCTS ARE EQUAL ON ANY FEATURES THAT ARE NOT INCLUDED ON THE CARDS.</p> <p>THIS IS A VERY IMPORTANT PART OF THE STUDY. PLEASE TAKE YOUR TIME AS WE REALISE THIS TASK REQUIRES CAREFUL CONSIDERATION.</p> <p><b>WAIT UNTIL THE NURSE HAS SORTED ALL THE CARDS INTO THREE PILES THEN CONTINUE</b></p> <p>I WOULD NOW LIKE YOU TO RANK THESE 32 CARDS FROM TOP TO BOTTOM, STARTING WITH THE PRODUCT YOU ARE MOST INTERESTED IN USING FOR HAEMOPHILIA ON THE TOP, THROUGH TO THE PRODUCT YOU ARE LEAST INTERESTED IN USING ON THE BOTTOM.</p> <p>PLEASE BEGIN BY RANKING THESE PRODUCTS IN THE "MOST INTERESTED" PILE.</p> <p>AFTER "MOST INTERESTED" PILE IS RANKED, ASK THE NURSE TO CONTINUE WITH THE PILE OF PRODUCTS HE/SHE "MIGHT USE" AND THEN FINALLY RANK THE "LEAST INTERESTED" PILE.</p> <p><b>ONCE THE NURSE HAS FINISHED SAY</b></p> <p>PLEASE READ OUT THE NUMBERS OF THE CARDS IN THE ORDER YOU HAVE ARRANGED THEM. THE FIRST NUMBER YOU READ OUT SHOULD BE THE PRODUCT YOU ARE <u>MOST</u> INTERESTED IN USING AND THE LAST NUMBER YOU READ OUT SHOULD BE THE PRODUCT YOU ARE <u>LEAST</u> INTERESTED IN USING.</p> <p><b>RECORD RESPONSES ON NEXT PAGE</b></p>		

		(1)-(2) 13	(3)-(11) REPEAT
<b>WRITE IN EACH NUMBER IN THE APPROPRIATE COLUMN BELOW</b>			
RANK	PRODUCT CARD NUMBER	RANK	PRODUCT CARD NUMBER
1 (MOST LIKELY)	(12) (13) <input type="text"/> <input type="text"/>	17	(44) (45) <input type="text"/> <input type="text"/>
	(14) (15) <input type="text"/> <input type="text"/>	18	(46) (47) <input type="text"/> <input type="text"/>
2	(16) (17) <input type="text"/> <input type="text"/>	19	(48) (49) <input type="text"/> <input type="text"/>
3	(18) (19) <input type="text"/> <input type="text"/>	20	(50) (51) <input type="text"/> <input type="text"/>
4	(20) (21) <input type="text"/> <input type="text"/>	21	(52) (53) <input type="text"/> <input type="text"/>
5	(22) (23) <input type="text"/> <input type="text"/>	22	(54) (55) <input type="text"/> <input type="text"/>
6	(24) (25) <input type="text"/> <input type="text"/>	23	(56) (57) <input type="text"/> <input type="text"/>
7	(26) (27) <input type="text"/> <input type="text"/>	24	(58) (59) <input type="text"/> <input type="text"/>
8	(28) (29) <input type="text"/> <input type="text"/>	25	(60) (61) <input type="text"/> <input type="text"/>
9	(30) (31) <input type="text"/> <input type="text"/>	26	(62) (63) <input type="text"/> <input type="text"/>
10	(32) (33) <input type="text"/> <input type="text"/>	27	(64) (65) <input type="text"/> <input type="text"/>
11	(34) (35) <input type="text"/> <input type="text"/>	28	(66) (67) <input type="text"/> <input type="text"/>
12	(36) (37) <input type="text"/> <input type="text"/>	29	(68) (69) <input type="text"/> <input type="text"/>
13	(38) (39) <input type="text"/> <input type="text"/>	30	(70) (71) <input type="text"/> <input type="text"/>
14	(40) (41) <input type="text"/> <input type="text"/>	31	(72) (73) <input type="text"/> <input type="text"/>
15	(42) (43) <input type="text"/> <input type="text"/>	32 (LEAST LIKELY)	(74) (75) <input type="text"/> <input type="text"/>
16	<input type="text"/> <input type="text"/>		

No	Question / Answer	Code	Score
Q13	Considering the potential product that you ranked as the one you would be most interested in using, what are your reasons for ranking it first? <b>PROBE FULLY</b>		
		(76)	
		(78)	
Q14	Considering the potential product that you ranked as the one you would be most likely to use, how interested would you be in using it in the haemophilia A patients treated at this centre? Would you say you were <b>SHOW CARD 2</b>		
		(79)	
	Not at all interested	1	
	Not very interested	2	
	Neither interested nor disinterested	3	
	Fairly interested	4	
	Very interested	5	
	Don't know	6	

THANK AND CLOSE

J500398  
Version 3 (Final)  
23/11/1999

## **CARD A**

### **Nurses**

#### ***Human or animal derived protein***

- used in manufacturing (culturing) and in the final formulation (for stabilising)
- used in manufacturing (culturing), but not in the final formulation (for stabilising)
- not used at all

#### ***Continuous infusion***

- an approved indication
- product has capability, but not approved (label indication)
- not possible (to be used for continuous infusion)

#### ***Diluent volume per vial***

- 2.5ml
- 5ml
- 10ml

#### ***Higher number of activity units per vial***

- 1,000 i.u. per vial
- 1,250 i.u. per vial
- 1,500 i.u. per vial
- 2,000 i.u. per vial

#### ***Assay issue***

- requires one-stage assay
- requires chromogenic assay (not available in every hospital)

#### ***Room temperature storage***

- Cannot be stored at room temperature (requires refrigeration)
- 3 months
- 6 months
- 1 year
- 2+ years

#### ***Reconstitution***

- current standard (two vials) with transfer needles
- current standard, with needleless reconstitution/mixing
- single step procedure (i.e. pre-filled, ready-to-use syringe)

J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 1**

***Human or animal derived protein***

- used in manufacturing (culturing) and in the final formulation (for stabilising)

***Continuous infusion***

- product has capability, but not approved (label indication)

***Diluent volume per vial***

- 10ml

***Higher number of activity units per vial***

- 1,500 i u per vial

***Assay issue***

- requires one-stage assay

***Room temperature storage***

- 1 year

***Reconstitution***

- single step procedure (i.e. pre-filled, ready-to-use syringe)

J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 2**

***Human or animal derived protein***

- used in manufacturing (culturing) and in the final formulation (for storage)

***Continuous infusion***

- not possible (to be used for continuous infusion)

***Diluent volume per vial***

- 5ml

***Higher number of activity units per vial***

- 1,250 i u per vial

***Assay issue***

- requires chromogenic assay (not available in every hospital)

***Room temperature storage***

- 2+ years

***Reconstitution***

- current standard, with needleless reconstitution/mixing

J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 3**

*Human or animal derived protein*  
➤ not used at all

*Continuous infusion*  
➤ an approved indication

*Diluent volume per vial*  
➤ 10ml

*Higher number of activity units per vial*  
➤ 2,000 i.u. per vial

*Assay issue*  
➤ requires chromogenic assay (not available in every hospital)

*Room temperature storage*  
➤ Cannot be stored at room temperature (requires refrigeration)

*Reconstitution*  
➤ current standard (two vials) with transfer needles

J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 4**

*Human or animal derived protein*  
➤ not used at all

*Continuous infusion*  
➤ not possible (to be used for continuous infusion)

*Diluent volume per vial*  
➤ 5ml

*Higher number of activity units per vial*  
➤ 1,000 i u per vial

*Assay issue*  
➤ requires one-stage assay

*Room temperature storage*  
➤ 6 months

*Reconstitution*  
➤ current standard, with needleless reconstitution/mixing



J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 5**

***Human or animal derived protein***

- used in manufacturing (culturing), but not in the final formulation (for stabilising)

***Continuous infusion***

- product has capability, but not approved (label indication)

***Diluent volume per vial***

- 10ml

***Higher number of activity units per vial***

- 2,000 i u per vial

***Assay issue***

- requires one-stage assay

***Room temperature storage***

- 2+ years

***Reconstitution***

- current standard with needleless reconstitution/mixing

J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 6**

***Human or animal derived protein***

- used in manufacturing (culturing), but not in the final formulation for storage

***Continuous infusion***

- not possible (to be used for continuous infusion)

***Diluent volume per vial***

- 5ml

***Higher number of activity units per vial***

- 1,000 i u per vial

***Assay issue***

- required chromogenic assay (not available in every hospital)

***Room temperature storage***

- 1 year

***Reconstitution***

- current standard (two vials) with transfer needles

J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 7**

*Human or animal derived protein*  
➤ not used at all

*Continuous infusion*  
➤ an approved indication

*Diluent volume per vial*  
➤ 10ml

*Higher number of activity units per vial*  
➤ 1,500 i u per vial

*Assay issue*  
➤ requires chromogenic assay (not available in ever / hospital)

*Room temperature storage*  
➤ 6 months

*Reconstitution*  
➤ current standard, with needleless reconstitution/mixing

J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 8**

*Human or animal derived protein*

- not used at all

*Continuous infusion*

- not possible (to be used for continuous infusion)

*Diluent volume per vial*

- 5ml

*Higher number of activity units per vial*

- 1,250 i u per vial

*Assay issue*

- requires one-stage assay

*Room temperature storage*

- Cannot be stored at room temperature (requires refrigeration)

*Reconstitution*

- single step procedure (i.e. pre-filled, ready-to-use syringe)

J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 9**

***Human or animal derived protein***

- used in manufacturing (culturing) and in the final formulation (for stabilising)

***Continuous infusion***

- product has capability, but not approved (label indication)

***Diluent volume per vial***

- 2.5ml

***Higher number of activity units per vial***

- 1,250 i u per vial

***Assay issue***

- requires one-stage assay

***Room temperature storage***

- 6 months

***Reconstitution***

- current standard (two vials) with transfer needles

J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 10**

***Human or animal derived protein***

- used in manufacturing (culturing) and in the final formulation (for stabilising)

***Continuous infusion***

- not possible (to be used for continuous infusion)

***Diluent volume per vial***

- 5ml

***Higher number of activity units per vial***

- 1,500 i.u. per vial

***Assay issue***

- requires chromogenic assay (not available in every hospital)

***Room temperature storage***

- Cannot be stored at room temperature (requires refrigeration)

***Reconstitution***

- current standard, with needleless reconstitution/mixing

J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 11**

*Human or animal derived protein*  
➤ not used at all

*Continuous infusion*  
➤ an approved indication

*Diluent volume per vial*  
➤ 2.5ml

*Higher number of activity units per vial*  
➤ 1,000 i.u. per vial

*Assay issue*  
➤ requires chromogenic assay (not available in every hospital)

*Room temperature storage*  
➤ 2+ years

*Reconstitution*  
➤ single step procedure (i.e. pre-filled, ready-to-use syringe)

J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 12**

***Human or animal derived protein***

- not used at all

***Continuous infusion***

- not possible (to be used for continuous infusion)

***Diluent volume per vial***

- 5ml

***Higher number of activity units per vial***

- 2,000 i u. per vial

***Assay issue***

- requires one-stage assay

***Room temperature storage***

- 1 year

***Reconstitution***

- current standard, with needleless reconstitution/mixing



J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 13**

***Human or animal derived protein***

- used in manufacturing (culturing), but not in the final formulation (for stabilising)

***Continuous infusion***

- product has capability, but not approved (label indication)

***Diluent volume per vial***

- 2.5ml

***Higher number of activity units per vial***

- 1,000 i u per vial

***Assay issue***

- requires one-stage assay

***Room temperature storage***

- Cannot be stored at room temperature (requires refrigeration)

***Reconstitution***

- current standard, with needleless reconstitution/mixing

J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 14**

***Human or animal derived protein***

- used in manufacturing (culturing), but not in the final formulation (for stabilising)

***Continuous infusion***

- not possible (to be used for continuous infusion)

***Diluent volume per vial***

- 5ml

***Higher number of activity units per vial***

- 2,000 i u per vial

***Assay issue***

- requires chromogenic assay (not available in every hospital)

***Room temperature storage***

- 6 months

***Reconstitution***

- single step procedure (i.e. pre-filled, ready-to-use syringe)

J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 15**

*Human or animal derived protein*  
➤ not used at all

*Continuous infusion*  
➤ an approved indication

*Diluent volume per vial*  
➤ 2.5ml

*Higher number of activity units per vial*  
➤ 1,250 i u per vial

*Assay issue*  
➤ requires chromogenic assay (not available in every hospital)

*Room temperature storage*  
➤ 1 year

*Reconstitution*  
➤ current standard, with needleless reconstitution/mixing

J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 16**

***Human or animal derived protein***

- not used at all

***Continuous infusion***

- not possible (to be used for continuous infusion)

***Diluent volume per vial***

- 5ml

***Higher number of activity units per vial***

- 1,500 i u per vial

***Assay issue***

- requires one-stage assay

***Room temperature storage***

- 2+ years

***Reconstitution***

- current standard (two vials) with transfer needles

J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 17**

***Human or animal derived protein***

- not used at all

***Continuous infusion***

- not possible (to be used for continuous infusion)

***Diluent volume per vial***

- 2.5ml

***Higher number of activity units per vial***

- 1,500 i u per vial

***Assay issue***

- requires one-stage assay

***Room temperature storage***

- 3 months

***Reconstitution***

- current standard, with needleless reconstitution/mixing

J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 18**

***Human or animal derived protein***

- not used at all

***Continuous infusion***

- product has capability, but not approved (label indication)

***Diluent volume per vial***

- 5ml

***Higher number of activity units per vial***

- 1,250 i u per vial

***Assay issue***

- requires chromogenic assay (not available in every hospital)

***Room temperature storage***

- 2+ years

***Reconstitution***

- current standard (two vials) with transfer needles

J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 20**

***Human or animal derived protein***

- used in manufacturing (culturing) and in the final formulation (for stabilising,

***Continuous infusion***

- an approved indication

***Diluent volume per vial***

- 5ml

***Higher number of activity units per vial***

- 1,000 i u per vial

***Assay issue***

- requires one-stage assay

***Room temperature storage***

- 6 months

***Reconstitution***

- single step procedure (i.e. pre-filled, ready-to-use syringe)

J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 21**

*Human or animal derived protein*

- not used at all

*Continuous infusion*

- not possible (to be used for continuous infusion)

*Diluent volume per vial*

- 2.5ml

*Higher number of activity units per vial*

- 2,000 i u per vial

*Assay issue*

- requires one-stage assay

*Room temperature storage*

- 2+ years

*Reconstitution*

- single step procedure (i.e. pre-filled, ready-to-use syringe)



J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 22**

***Human or animal derived protein***

- not used at all

***Continuous infusion***

- product has capability, but not approved (label indication)

***Diluent volume per vial***

- 5ml

***Higher number of activity units per vial***

- 1,000 i u per vial

***Assay issue***

- requires chromogenic assay (not available in every hospital)

***Room temperature storage***

- 3 months

***Reconstitution***

- current standard, with needleless reconstitution/mixing

J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 23**

***Human or animal derived protein***

- used in manufacturing (culturing), but not in the final formulation (for stabilising)

***Continuous infusion***

- not possible (to be used for continuous infusion)

***Diluent volume per vial***

- 2.5ml

***Higher number of activity units per vial***

- 1,500 i.u. per vial

***Assay issue***

- requires chromogenic assay (not available in every hospital)

***Room temperature storage***

- 6 months

***Reconstitution***

- current standard (two vials) with transfer needles

J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 24**

***Human or animal derived protein***

- used in manufacturing (culturing), but not in the final formulation (for stabilising)

***Continuous infusion***

- an approved indication

***Diluent volume per vial***

- 5ml

***Higher number of activity units per vial***

- 1,250 i u per vial

***Assay issue***

- requires one-stage assay

***Room temperature storage***

- Cannot be stored at room temperature (requires refrigeration)

***Reconstitution***

- current standard, with needleless reconstitution/mixing

J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 25**

***Human or animal derived protein***

- not used at all

***Continuous infusion***

- not possible (to be used for continuous infusion)

***Diluent volume per vial***

- 10ml

***Higher number of activity units per vial***

- 1,250 i u per vial

***Assay issue***

- requires one-stage assay

***Room temperature storage***

- 6 months

***Reconstitution***

- current standard, with needleless reconstitution/mixing

J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 26**

***Human or animal derived protein***

- not used at all

***Continuous infusion***

- product has capability, but not approved (label indication)

***Diluent volume per vial***

- 5ml

***Higher number of activity units per vial***

- 1,500 i u per vial

***Assay issue***

- requires chromogenic assay (not available in every hospital)

***Room temperature storage***

- Cannot be stored at room temperature (requires refrigeration)

***Reconstitution***

- single step procedure (i.e. pre-filled, ready-to-use syringe)

J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 27**

***Human or animal derived protein***

- used in manufacturing (culturing) and in the final formulation (for stabilising)

***Continuous infusion***

- not possible (to be used for continuous infusion)

***Diluent volume per vial***

- 10ml

***Higher number of activity units per vial***

- 1,000 i u per vial

***Assay issue***

- requires chromogenic assay (not available in every hospital)

***Room temperature storage***

- 2+ years

***Reconstitution***

- current standard, with needleless reconstitution/mixing

J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 28**

***Human or animal derived protein***

- used in manufacturing (culturing) and in the final formulation (for stabilising)

***Continuous infusion***

- an approved indication

***Diluent volume per vial***

- 5ml

***Higher number of activity units per vial***

- 2,000 i u per vial

***Assay issue***

- requires one-stage assay

***Room temperature storage***

- 3 months

***Reconstitution***

- current standard (two vials) with transfer needles

J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 29**

*Human or animal derived protein*

- not used at all

*Continuous infusion*

- not possible (to be used for continuous infusion)

*Diluent volume per vial*

- 10ml

*Higher number of activity units per vial*

- 1,000 i u per vial

*Assay issue*

- requires one-stage assay

*Room temperature storage*

- Cannot be stored at room temperature (requires refrigeration)

*Reconstitution*

- current standard (two vials) with transfer needles



J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 30**

***Human or animal derived protein***

- not used at all

***Continuous infusion***

- product has capability, but not approved (label indication)

***Diluent volume per vial***

- 5ml

***Higher number of activity units per vial***

- 2,000 i u per vial

***Assay issue***

- requires chromogenic assay (not available in every hospital)

***Room temperature storage***

- 6 months

***Reconstitution***

- current standard, with needleless reconstitution/mixing

J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 31**

***Human or animal derived protein***

- used in manufacturing (culturing), but not in the final formulation (for stabilising)

***Continuous infusion***

- not possible (to be used for continuous infusion)

***Diluent volume per vial***

- 10ml

***Higher number of activity units per vial***

- 1,250 i u per vial

***Assay issue***

- requires chromogenic assay (not available in every hospital)

***Room temperature storage***

- 3 months

***Reconstitution***

- single step procedure (i.e. pre-filled, ready-to-use syringe)

J500398  
Version 3 (Final)  
23/11/1999

**NURSE - CARD 32**

***Human or animal derived protein***

- used in manufacturing (culturing), but not in the final formulation (for stabilizing)

***Continuous infusion***

- an approved indication

***Diluent volume per vial***

- 5ml

***Higher number of activity units per vial***

- 1,500 i u per vial

***Assay issue***

- requires one-stage assay

***Room temperature storage***

- 2+ years

***Reconstitution***

- current standard, with needleless reconstitution/mixing

**Appendix I**  
**(c) Patients**

J500398  
Version 2 (Final)

(1)	(2)	(3)	(4) - (10)	(11)
14	0398			3
CC	V No	Country	Serial	PL

INTERNATIONAL HEALTH SURVEYS, LUDGATE HOUSE, 245 BLACKFRIARS ROAD, LONDON SE1 9UL

**RECOMBINANT FVIII POSITIONING STUDY  
PATIENT SCREENING QUESTIONNAIRE**

Patient name \_\_\_\_\_

Address \_\_\_\_\_

(please print) \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Telephone No \_\_\_\_\_

\_\_\_\_\_

**INTRODUCTION**

GOOD MORNING/AFTERNOON MY NAME IS \_\_\_\_\_ FROM INTERNATIONAL HEALTH SURVEYS, AN INDEPENDENT MARKET RESEARCH AGENCY BASED IN LONDON, WHICH SPECIALISE IN CONDUCTING SURVEYS AMONG MEMBERS OF THE MEDICAL PROFESSION AND PATIENTS

WE ARE CURRENTLY CONDUCTING AN INTERNATIONAL STUDY WITH DOCTORS, NURSES AND PATIENTS ON THE SUBJECT OF HAEMOPHILIA A

YOUR NAME HAS BEEN GIVEN TO US BY \_\_\_\_\_

THE INTERVIEW WILL LAST UP TO 45 MINUTES THE INFORMATION YOU PROVIDE WILL BE COMBINED WITH THAT OF OTHER PATIENTS YOUR IDENTIFY WILL NOT BE REVEALED TO ANY THIRD PARTY STRICT CONFIDENTIALITY IS ASSURED

WOULD YOU BE WILLING TO TAKE PART IN OUR SURVEY?

COULD I FIRST ASK YOU A FEW QUESTIONS TO ASSESS YOUR ELIGIBILITY FOR THIS SURVEY

No	Question / Answer	Code	Skip to
Q1	Could I begin by confirming whether you personally suffer from haemophilia A or whether you have a child who suffers from the condition?	(12)	
	Respondent personally	1	
	Child	2	
	<b>PROCEED ACCORDING TO QUOTAS</b>		
Q2	Do you/does your child currently use a <b>recombinant</b> Factor VIII product to treat the haemophilia A (e.g. Helixate, Kogenate, Recombinate or Refacto)?	(13)	
	<b>ADAPT PRODUCTS ACCORDING TO COUNTRY</b>		
	Yes	1	<b>RECRUIT</b>
	No	2	<b>THANK &amp; CLOSE</b>
	Don't know	V	

INTERNATIONAL HEALTH SURVEYS, LUDGATE HOUSE, 245 BLACKFRIARS ROAD, LONDON SE1 9UL

RECOMBINANT FACTOR VIII POSITIONING STUDY  
 PATIENT QUESTIONNAIRE

NAME ..... (PRINT)  
 ADDRESS ..... (PRINT)  
 POST CODE ..... (PRINT)  
 TEL NO ..... (PRINT)

**RESPONDENT TYPE**

(12)  
 Haemophilia sufferer 1  
 Parent of child with haemophilia 2

**AGE (OF CHILD, if appropriate)**

(13) (14)  
 [ ] years (15)  
 Refused X

**SOCIAL CLASS (UK VERSION)**

(16)  
 A 1  
 B 2  
 C1 3  
 C2 4  
 D 5  
 E 6  
 Refused X

**REGION (UK VERSION)**

(17)  
 Scotland 1  
 Tyne Tees 2  
 Granada 3  
 Yorkshire 4  
 Central 5  
 Harlech 6  
 Anglia 7  
 Carlton/LWT 8  
 Mendian 9  
 West Country TV 0

**COLUMNS (18)-(64) BLANK**

TIME STARTED ..... DATE OF INTERVIEW (65) (66) (67) (68) (69) (70) (71) (72) (73) (74)  
 TIME FINISHED ..... INTERVIEWED BY (75) (76) (77) (78) (79)  
 O U O (80) 1 2 3 4 5 6 7 8 9 O X V

RESPONDENT SIGNATURE FOR FEE

INTERVIEWER SIGNATURE

(signature) (signature)  
 THIS INTERVIEW HAS BEEN CONDUCTED WITHIN THE TERMS OUTLINED BY THE MRS CODE OF CONDUCT

No	Question / Answer	Code	Score
Q1	<p>How long ago is it since you were/your child was diagnosed with haemophilia A?</p> <p><b>RECORD AS YEARS <u>OR</u> MONTHS</b></p> <p>(12) (13) years <u>OR</u> (14) (15) months</p> <p>Less than 1 month</p> <p>Don't know</p>	<p>(16)</p> <p>X</p> <p>V</p>	
Q2	<p>For how long have you/has your child been using a <u>recombinant</u> Factor VIII product?</p> <p><b>RECORD AS YEARS <u>OR</u> MONTHS</b></p> <p>(17) (18) years <u>OR</u> (19) (20) months</p> <p>Less than 1 month</p> <p>Don't know</p> <p><b>ENSURE LESS THAN EQUAL TO ANSWER TO Q1</b></p>	<p>(21)</p> <p>X</p> <p>V</p>	
Q3	<p>Do you/does your child currently take Factor VIII regularly as prophylaxis/prevention or do you/does your child only take it on an as needed basis?</p> <p>Regular prophylaxis/prevention</p> <p>As needed</p> <p>Other (please specify)</p> <p>Don't know</p>	<p>(22)</p> <p>1</p> <p>2</p> <p>(23)</p> <p>X</p> <p>V</p>	
Q4	<p>Do you/does your child have a catheter (Portacath) for the administration of the Factor VIII?</p> <p>Yes</p> <p>No</p> <p>Don't know</p>	<p>(24)</p> <p>1</p> <p>2</p> <p>V</p>	

QUESTION / ANSWER		Code	Skip to
Q5a	Which specific brand of Factor VIII products are you/ is your child currently using?		
<b>RESPONDENT/CHILD MUST BE USING A RECOMBINANT PRODUCT (SEE SCREENER)</b>			
<b>RECORD IN APPROPRIATE COLUMN BELOW</b>			
Q5b	Which, if any, <u>other</u> brand(s) of Factor VIII have you/ has your child used in the past?		
<b>RECORD IN APPROPRIATE COLUMN BELOW</b>			
		Q5a Currently (25)	Q5b Past (27)
	<u>Recombinant</u>		
	Bioclone	1	1
	Helixate	2	2
	Kogenate	3	3
	Recombinate	4	4
	Refacto	5	5
(ONLY FOR Q5b)	<u>Human plasma</u>		(28)
	Alphanate		1
	Benlate		2
	Contact F		3
	Crosseight M		4
	Emoclot		5
	Fhandi		6
	Haemate-P/Humate P		7
	Haemoctin SDH		8
	Hemofil M		9
	Immunate		0
	Innobrand		X
	Koate DVI		V
			(29)
	Kryobulin		1
	Monarc M		2
	Monoclone-P		3
	Nordiate		4
	Octenate		5
	Octinatv M		6
	Profilate		7
	Replenate		8
	Uman		9
		(26)	(30)
	Others (please specify)	X	X
Q5a	-----		
Q5b	-----		
(ONLY FOR Q5b) No other brand used in past			0
	Don't know	V	V



NO	Question / Answer	Code	Sec
Q6a	<p>How satisfied are you with your/your child's current recombinant Factor VIII treatment? Would you say you were</p> <p><b>SHOW CARD 1</b></p> <div style="text-align: right;"> <p>Very dissatisfied 1</p> <p>Fairly dissatisfied 2</p> <p>Neither satisfied nor dissatisfied 3</p> <p>Fairly satisfied 4</p> <p>Very satisfied 5</p> <p>Don't know V</p> </div>	<p>(31)</p> <p>Q6a</p> <p>Q6a</p> <p>Q6a</p> <p>Q6a</p>	
Q6b	<p>Why do you say you are dissatisfied with your/your child's current recombinant Factor VIII treatment?</p> <p><b>PROBE FULLY</b></p>	<p>32</p> <p>(33)</p> <p>34)</p>	Q6b
Q6c	<p>Why do you say you are satisfied with your/your child's current recombinant Factor VIII treatment?</p> <p><b>PROBE FULLY</b></p>	<p>35)</p> <p>36)</p> <p>37</p>	Q6c

Q7	What factors influence your choice of Factor VIII treatment for haemophilia A? PROBE FULLY	Code	Skip to
		(38)	
	Recombinant vs human plasma-derived	1	
	Albumin/protein content	2	
	Efficacy/response rates	3	
	Duration of effect/half life	4	
	Speed of response/effect	5	
	Safety (unspecified)	6	
	Lack of adverse reactions	7	
	Lack of (viral) contamination	8	
	Range of potencies/vial sizes	9	
		(39)	
	Diluent/infusion volume	1	
	Storage (refrigeration vs room temperature)	2	
	Shelf-life	3	
	Delivery to patient's home	4	
	Ease of reconstitution	5	
	Speed of reconstitution	6	
	Ease of administration	7	
	Cost	8	
		(40)	
		(41)	
		(42)	
		(43)	
	Other (please specify)	X	
	-----		
	Have no influence on choice of product	0	
	Don't know	V	

No	Question / Answer	Code	Score
Q8	What improvements would you like to see made to recombinant Factor VIII products?	(44)	
	<b>PROBE FULLY</b>		
	Reduced use of protein/albumin	1	
	Improved efficacy/response	2	
	Longer lasting effect/longer half-life	3	
	Improved speed of response/effect	4	
	Improved safety (unspecified)	5	
	Fewer adverse reactions	6	
	Reduced/no (viral) contamination	7	
	Higher potencies/larger vial sizes	8	
	Reduced volume of diluent/infusion	9	
		(45)	
	Improved storage (refrigeration not required)	1	
	Longer shelf-life	2	
	Clearer storage instructions	3	
	Improved packaging/less wastage of ancillary products	4	
	Improved/easier reconstitution	5	
	Faster reconstitution	6	
	Improved/easier administration	7	
	Reduced cost	8	
		46	
		47	
		48	
		49	
	Other (please specify)	X	
	-----		
	-----		
	Don't know	V	

ID	QUESTION / ANSWER	CODE	Skip to
	<p><b>HAND PATIENT SHOW CARD A</b></p> <p>THIS CARD LISTS SEVERAL FEATURES ON WHICH POTENTIAL NEW RECOMBINANT PRODUCTS FOR HAEMOPHILIA A MIGHT DIFFER PLEASE TAKE A FEW MINUTES TO READ OVER THE FEATURES AND THEIR VARIOUS LEVELS, AS THIS INFORMATION WILL MAKE THE FOLLOWING EXERCISE RUN MORE SMOOTHLY</p> <p><b>ALLOW RESPONDENT TIME TO READ ALL INFORMATION ON THE CARD</b></p> <p>I HAVE HERE 25 CARDS, EACH DESCRIBING A POTENTIAL RECOMBINANT FACTOR VIII PRODUCT WITH A UNIQUE COMBINATION OF FEATURES NO TWO CARDS ARE EXACTLY THE SAME FOR THE PURPOSE OF THIS EXERCISE, PLEASE IMAGINE THAT THESE 25 POTENTIAL PRODUCTS ARE THE ONLY ONES AVAILABLE FOR THE TREATMENT OF HAEMOPHILIA A</p> <p><b>HAND PATIENT SHUFFLED CARDS</b></p> <p>PLEASE SORT THESE 25 POTENTIAL PRODUCTS INTO <u>3 PILES</u> ACCORDING TO YOUR INTEREST IN USE OF THEM ONE PILE SHOULD CONTAIN THOSE PRODUCTS THAT YOU WOULD BE <u>MOST</u> INTERESTED IN USING, ONE THOSE PRODUCTS THAT YOU <u>MIGHT</u> CONSIDER USING AND ONE THOSE PRODUCTS THAT YOU WOULD BE <u>LEAST</u> INTERESTED IN USING YOU CAN HAVE ANY NUMBER OF CARDS IN EACH OF THE 3 PILES</p> <p>ASSUME THESE PRODUCTS ARE EQUAL ON ANY FEATURES THAT ARE NOT INCLUDED ON THE CARDS</p> <p>THIS IS A VERY IMPORTANT PART OF THE STUDY PLEASE TAKE YOUR TIME AS WE REALISE THIS TASK REQUIRES CAREFUL CONSIDERATION</p> <p><b>WAIT UNTIL THE PATIENT HAS SORTED ALL THE CARDS INTO THREE PILES, THEN CONTINUE</b></p> <p>I WOULD NOW LIKE YOU TO RANK THESE 25 CARDS FROM TOP TO BOTTOM, STARTING WITH THE PRODUCT YOU ARE MOST INTERESTED IN USING ON THE TOP, THROUGH TO THE PRODUCT YOU ARE LEAST INTERESTED IN USING ON THE BOTTOM</p> <p>PLEASE BEGIN BY RANKING THESE PRODUCTS IN THE "MOST INTERESTED" PILE</p> <p>AFTER "MOST INTERESTED" PILE IS RANKED, ASK THE PATIENT TO CONTINUE WITH THE PILE OF PRODUCTS HE/SHE "MIGHT USE" AND THEN FINALLY RANK THE "LEAST INTERESTED" PILE.</p> <p><b>ONCE THE PATIENT HAS FINISHED SAY:</b></p> <p>PLEASE READ OUT THE NUMBERS OF THE CARDS IN THE ORDER YOU HAVE ARRANGED THEM THE FIRST NUMBER YOU READ OUT SHOULD BE THE PRODUCT YOU ARE <u>MOST</u> INTERESTED IN USING AND THE LAST NUMBER YOU READ OUT SHOULD BE THE PRODUCT YOU ARE <u>LEAST</u> INTERESTED IN USING</p> <p><b>RECORD RESPONSES ON NEXT PAGE</b></p>		

WRITE IN EACH NUMBER IN THE APPROPRIATE COLUMN BELOW

RANK	PRODUCT CARD NUMBER	RANK	PRODUCT CARD NUMBER
1 (MOST LIKELY)	(12) (13)	17	(44) (45)
	(14) (15)	18	(46) (47)
2	(16) (17)	19	(48) (49)
3	(18) (19)	20	(50) (51)
4	(20) (21)	21	(52) (53)
5	(22) (23)	22	(54) (55)
6	(24) (25)	23	(56) (57)
7	(26) (27)	24	(58) (59)
8	(28) (29)	25	(60) (61)
9	(30) (31)		
10	(32) (33)		
11	(34) (35)		
12	(36) (37)		
13	(38) (39)		
14	(40) (41)		
15	(42) (43)		
16			

NO	Question / Answer	Code	Skip to
Q9	Considering the potential product that you ranked as the one you would be most interested in using, what are your reasons for ranking it first? <b>PROBE FULLY</b>	(62)	
		(63)	
		(64)	
Q10	Considering the potential product that you ranked as the one you would be most likely to use, how interested would you be in using it (in your child)? Would you say you were <b>SHOW CARD 2</b>	(65)	
	Not at all interested	1	
	Not very interested	2	
	Neither interested nor disinterested	3	
	Fairly interested	4	
	Very interested	5	
	Don't know	V	
<b>Q11-13 USA only</b>			
Q11	Considering the potential product that you ranked as the one you would be most likely to use, do you believe a price premium for that product would be acceptable?	(66)	
	Yes	1	Q12
	No	2	THANK AND CLOSE
	Don't know	V	
Q12	What percentage price increase over currently available recombinant products would you consider to be acceptable?	(70)	
	(67) (68) (69) % enter percentage	X	Q13
	Depends	V	THANK AND CLOSE
	Don't know		
<b>GO TO Q13 IF 'DEPENDS', OTHERWISE THANK AND CLOSE</b>			
Q13	On what would the acceptable level of price increase depend? <b>PROBE FULLY</b>	(71)	
		(72)	
		(73)	

THANK AND CLOSE

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## **CARD A**

### **Patients**

#### ***Human or animal derived protein***

- used in manufacturing (culturing) and in the final formulation (for stabilising)
- used in manufacturing (culturing), but not in the final formulation (for stabilising)
- not used at all

#### ***Diluent volume per vial***

- 2.5ml
- 5ml
- 10ml

#### ***Higher number of activity units per vial***

- 1,000 i.u. per vial
- 1,250 i.u. per vial
- 1,500 i.u. per vial
- 2,000 i.u. per vial

#### ***Room temperature storage***

- Cannot be stored at room temperature (requires refrigeration)
- 3 months
- 6 months
- 1 year
- 2+ years

#### ***Reconstitution***

- current standard (two vials) with transfer needles
- current standard, with needleless reconstitution/mixing
- single step procedure (i.e. pre-filled, ready-to-use syringe)

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**PATIENT - CARD 1**

***Human or animal derived protein***

- used in manufacturing (culturing), but not in the final formulation (for stabilising)

***Diluent volume per vial***

- 2.5ml

***Higher number of activity units per vial***

- 2,000 i u per vial

***Room temperature storage***

- Cannot be stored at room temperature (requires refrigeration)

***Reconstitution***

- current standard (two vials) with transfer needles



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**PATIENT - CARD 2**

*Human or animal derived protein*

- used in manufacturing (culturing) and in the final formulation (for stability)

*Diluent volume per vial*

- 2.5ml

*Higher number of activity units per vial*

- 1,500 i.u. per vial

*Room temperature storage*

- 1 year

*Reconstitution*

- current standard (two vials) with transfer needles

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23/11/1999

**PATIENT - CARD 3**

***Human or animal derived protein***

- used in manufacturing (culturing), but not in the final formulation (for stabilising)

***Diluent volume per vial***

- 10ml

***Higher number of activity units per vial***

- 1,250 i u per vial

***Room temperature storage***

- 2+ years

***Reconstitution***

- current standard, with needleless reconstitution/mixing

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23/11/1999

**PATIENT - CARD 4**

*Human or animal derived protein*

➤ not used at all

*Diluent volume per vial*

➤ 5ml

*Higher number of activity units per vial*

➤ 1,500 i u per vial

*Room temperature storage*

➤ Cannot be stored at room temperature (requires refrigeration)

*Reconstitution*

➤ current standard, with needleless reconstitution/mixing

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Version 3 (Final)  
23/11/1999

**PATIENT - CARD 5**

*Human or animal derived protein*  
➤ not used at all

*Diluent volume per vial*  
➤ 5ml

*Higher number of activity units per vial*  
➤ 1,000 i u per vial

*Room temperature storage*  
➤ 6 months

*Reconstitution*  
➤ current standard (two vials) with transfer needles

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Version 3 (Final)  
23/11/1999

**PATIENT - CARD 6**

*Human or animal derived protein*  
➤ not used at all

*Diluent volume per vial*  
➤ 10ml

*Higher number of activity units per vial*  
➤ 2,000 i u per vial

*Room temperature storage*  
➤ 1 year

*Reconstitution*  
➤ single step procedure (i.e. pre-filled, ready-to-use syringe)

GH001470

J500398  
Version 3 (Final)  
23/11/1999

**PATIENT - CARD 7**

*Human or animal derived protein*

- used in manufacturing (culturing), but not in the final formulation (for stabilising)

*Diluent volume per vial*

- 2.5ml

*Higher number of activity units per vial*

- 1,000 i u per vial

*Room temperature storage*

- 1 year

*Reconstitution*

- current standard, with needleless reconstitution/mixing

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23/11/1999

**PATIENT - CARD 8**

***Human or animal derived protein***

- used in manufacturing (culturing), but not in the final formulation (for stat's use)

***Diluent volume per vial***

- 10ml

***Higher number of activity units per vial***

- 1,250 i u per vial

***Room temperature storage***

- Cannot be stored at room temperature (requires refrigeration)

***Reconstitution***

- single step procedure (i.e. pre-filled, ready-to-use syringe)

J500398  
Version 3 (Final)  
23/11/1999

**PATIENT - CARD 9**

***Human or animal derived protein***

- used in manufacturing (culturing), but not in the final formulation (for stabilising)

***Diluent volume per vial***

- 2.5ml

***Higher number of activity units per vial***

- 1,250 i u per vial

***Room temperature storage***

- 6 months

***Reconstitution***

- single step procedure (i.e. pre-filled, ready-to-use syringe)



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23/11/1999

**PATIENT - CARD 10**

*Human or animal derived protein*  
➤ not used at all

*Diluent volume per vial*  
➤ 2.5ml

*Higher number of activity units per vial*  
➤ 2,000 i u per vial

*Room temperature storage*  
➤ 3 months

*Reconstitution*  
➤ single step procedure (i.e. pre-filled, ready-to-use syringe)

GH001474

J500398  
Version 3 (Final)  
23/11/1999

**PATIENT - CARD 11**

***Human or animal derived protein***

- used in manufacturing (culturing), but not in the final formulation (for stabilising)

***Diluent volume per vial***

- 5ml

***Higher number of activity units per vial***

- 1,250 i u per vial

***Room temperature storage***

- 1 year

***Reconstitution***

- single step procedure (i.e. pre-filled, ready-to-use syringe)

J500398  
Version 3 (Final)  
23/11/1999

**PATIENT - CARD 12**

***Human or animal derived protein***

- used in manufacturing (culturing), but not in the final formulation (for stabilising)

***Diluent volume per vial***

- 2.5ml

***Higher number of activity units per vial***

- 1,500 i.u. per vial

***Room temperature storage***

- 6 months

***Reconstitution***

- single step procedure (i.e. pre-filled, ready-to-use syringe)

J500398  
Version 3 (Final)  
23/11/1999

**PATIENT - CARD 13**

***Human or animal derived protein***

- used in manufacturing (culturing), but not in the final formulation (for stabilising)

***Diluent volume per vial***

- 10ml

***Higher number of activity units per vial***

- 1,000 i u per vial

***Room temperature storage***

- 3 months

***Reconstitution***

- current standard (two vials) with transfer needles

GH001477

J500398  
Version 3 (Final)  
23/11/1999

**PATIENT - CARD 14**

*Human or animal derived protein*  
➤ not used at all

*Diluent volume per vial*  
➤ 10ml

*Higher number of activity units per vial*  
➤ 1,250 i u per vial

*Room temperature storage*  
➤ 6 months

*Reconstitution*  
➤ current standard (two vials) with transfer needles

GH001478

J500398  
Version 3 (Final)  
23/11/1999

**PATIENT - CARD 15**

*Human or animal derived protein*  
➤ not used at all

*Diluent volume per vial*  
➤ 2.5ml

*Higher number of activity units per vial*  
➤ 1,250 i u per vial

*Room temperature storage*  
➤ Cannot be stored at room temperature (requires refrigeration)

*Reconstitution*  
➤ current standard (two vials) with transfer needles

J500398  
Version 3 (Final)  
23/11/1999

**PATIENT - CARD 16**

*Human or animal derived protein*

➤ not used at all

*Diluent volume per vial*

➤ 2.5ml

*Higher number of activity units per vial*

➤ 1,000 i u per vial

*Room temperature storage*

➤ 2+ years

*Reconstitution*

➤ single step procedure (i.e. pre-filled, ready-to-use syringe)

J500398  
Version 3 (Final)  
23/11/1999

**PATIENT - CARD 17**

***Human or animal derived protein***

- used in manufacturing (culturing) and in the final formulation (for stabilising)

***Diluent volume per vial***

- 2.5ml

***Higher number of activity units per vial***

- 1,250 i.u. per vial

***Room temperature storage***

- 2+ years

***Reconstitution***

- current standard (two vials) with transfer needles



J500398  
Version 3 (Final)  
23/11/1999

**PATIENT - CARD 18**

***Human or animal derived protein***

- used in manufacturing (culturing) and in the final formulation (for stabilising)

***Diluent volume per vial***

- 5ml

***Higher number of activity units per vial***

- 1,250 i.u. per vial

***Room temperature storage***

- 3 months

***Reconstitution***

- single step procedure (i.e. pre-filled, ready-to-use syringe)

J500398

Version 3 (Final)  
23/11/1999

**PATIENT - CARD 19**

*Human or animal derived protein*

- used in manufacturing (culturing), but not in the final formulation (for stabilising)

*Diluent volume per vial*

- 5ml

*Higher number of activity units per vial*

- 2,000 i u per vial

*Room temperature storage*

- 2+ years

*Reconstitution*

- current standard (two vials) with transfer needles

GH001483

J500398  
Version 3 (Final)  
23/11/1999

**PATIENT - CARD 20**

***Human or animal derived protein***

- used in manufacturing (culturing) and in the final formulation (for stabilising)

***Diluent volume per vial***

- 10ml

***Higher number of activity units per vial***

- 1,000 i u per vial

***Room temperature storage***

- Cannot be stored at room temperature (requires refrigeration)

***Reconstitution***

- single step procedure

J500398  
Version 3 (Final)  
23/11/1999

**PATIENT – CARD 21**

***Human or animal derived protein***

- used in manufacturing (culturing) and in the final formulation (for stabilising)

***Diluent volume per vial***

- 10ml

***Higher number of activity units per vial***

- 2,000 i u per vial

***Room temperature storage***

- 6 months

***Reconstitution***

- current standard, with needleless reconstitution/mixing

J500398  
Version 3 (Final)  
23/11/1999

**PATIENT - CARD 22**

*Human or animal derived protein*  
➤ not used at all

*Diluent volume per vial*  
➤ 10ml

*Higher number of activity units per vial*  
➤ 1,250 i u per vial

*Room temperature storage*  
➤ 1 year

*Reconstitution*  
➤ current standard (two vials) with transfer needles

GH001486

J500398  
Version 3 (Final)  
23/11/1999

**PATIENT -- CARD 23**

*Human or animal derived protein*

➤ not used at all

*Diluent volume per vial*

➤ 10ml

*Higher number of activity units per vial*

➤ 1,500 i u per vial

*Room temperature storage*

➤ 2+ years

*Reconstitution*

➤ single step procedure (i e pre-filled, ready-to-use s/ringe)

J500398  
Version 3 (Final)  
23/11/1999

**PATIENT - CARD 24**

***Human or animal derived protein***

- used in manufacturing (culturing), but not in the final formulation (for stabilising)

***Diluent volume per vial***

- 10ml

***Higher number of activity units per vial***

- 1,500 i u per vial

***Room temperature storage***

- 3 months

***Reconstitution***

- current standard (two vials) with transfer needles

J500398  
Version 3 (Final)  
23/11/1999

**PATIENT - CARD 25**

*Human or animal derived protein*  
➤ not used at all

*Diluent volume per vial*  
➤ 2.5ml

*Higher number of activity units per vial*  
➤ 1,250 i u per vial

*Room temperature storage*  
➤ 3 months

*Reconstitution*  
➤ current standard, with needleless reconstitution/mixing

GH001489



## **Appendix II**

### **Trade-off/conjoint**

- (a) Attribute list**
- (b) Statistical results**
- (c) Background**

**500398 – Haemophilia**

**Attributes for conioint**

- 1      *Human protein***
  - i)      used in manufactunng and stabilising (final formulation)
  - ii)     used in manufactunng (cultunng), but not in the final formulation (for stabilising)
  - iii)    not used at all
  
- 2      *Continuous infusion***
  - i)      an approved indication
  - ii)     product has capability, but not approved (label indication)
  - iii)    not possible (to be used for continuous infusion)
  
- 3      *Diluent volume***
  - i)      2.5ml
  - ii)     5ml
  - iii)    10ml
  
- 4      *High potency***
  - i)      1,000 i u
  - ii)     1,250 i u
  - iii)    1,500 i u
  - iv)    2,000 i u
  
- 5      *Assay issue***
  - i)      requires one-stage assay
  - ii)     requires chromogenic assay (not available in every hospital)
  
- 6      *Room temperature storage***
  - i)      Cannot be stored at room temperature (requires refrigeration)
  - ii)     3 months
  - iii)    6 months
  - iv)    1 year
  - v)    2+ years

**7      *Reconstitution***

- i)      current standard (two vials) with transfer needles
- ii)     current standard, with needleless reconstitution mixing
- iii)    single step procedure (i.e. pre-filled, ready-to-use syringe)

**8      *rFVIII molecule***

- i)      full length
- ii)     B-domain deleted

**Doctors**

- 1   *Human protein***
- 2   *Continuous infusion***
- 3   *Diluent volume***
- 4   *High potency***
- 5   *Assay issue***
- 6   *Room temperature storage***
- 8   *rFVIII molecule***

**Nurses**

- 1   *Human protein***
- 2   *Continuous infusion***
- 3   *Diluent volume***
- 4   *High potency***
- 5   *Assay issue***
- 6   *Room temperature storage***
- 7   *Reconstitution***

**Patients**

- 1   *Human protein***
- 3   *Diluent volume***
- 4   *High potency***
- 6   *Room temperature storage***
- 7   *Reconstitution***

J500398

Utility &  
Average  
Importances

Attributes	Doctors Mean	se	Nurses Mean	se	Patients Mean	se
<b>1 Human protein</b>	<b>39%</b>		<b>34%</b>		<b>45%</b>	
Used in manufacturing and stabilising (final formulation)	0 8	0 3	0 6	0 2	1 1	0 2
Used in manufacturing (culturing), but not in the final formulation (for stabilising)	4 1	0 4	4 2	0 5	2 7	0 3
Not used at all	11 2	0 6	10 2	0 8	9 1	0 4
<b>2 Continuous infusion</b>	<b>26%</b>		<b>22%</b>		<b>0%</b>	
An approved indication	7 3	0 5	6 6	0 7		
Product has capability, but not approved (label indication)	5 2	0 5	4 6	0 5		
Not possible (to be used for continuous infusion)	0 4	0 2	0 5	0 2		
<b>3 Diluent volume</b>	<b>1%</b>		<b>7%</b>		<b>3%</b>	
2 5ml	2 1	0 3	3 8	0 5	2 4	0 2
5ml	1 7	0 2	3 6	0 5	2 0	0 2
10ml	1 8	0 3	1 9	0 3	1 9	0 2
<b>4 High potency</b>	<b>3%</b>		<b>5%</b>		<b>6%</b>	
1,000 i.u.	1 8	0 2	1 4	0 3	2 0	0 2
1,250 i.u.	1 4	0 2	1 7	0 2	2 3	0 2
1,500 i.u.	2 1	0 2	2 1	0 3	3 1	0 2
2,000 i.u.	1 6	0 2	2 8	0 4	2 8	0 2
<b>5 Assay issue</b>	<b>11%</b>		<b>5%</b>		<b>0%</b>	
Requires one-stage assay	3 4	0 4	2 4	0 4		
Requires chromogenic assay (not available in every hospital)	0 5	0 1	0 9	0 2		
<b>6 Room temperature storage</b>	<b>19%</b>		<b>20%</b>		<b>34%</b>	
Cannot be stored at room temperature (requires refrigeration)	1 2	0 3	2 1	0 4	1 5	0 3
3 months	3 5	0 4	2 8	0 4	4 2	0 3
6 months	5 4	0 4	4 5	0 5	5 4	0 3
1 year	6 1	0 5	6 8	0 6	6 9	0 3
2+ years	6 2	0 5	7 7	0 7	7 6	0 4
<b>7 Reconstitution</b>	<b>0%</b>		<b>7%</b>		<b>11%</b>	
Current standard (two vials) with transfer needles			0 9	0 2	1 5	0 1
Current standard, with needleless reconstitution/mixing			2 1	0 3	2 1	0 2
Single step procedure (i.e. pre-filled, ready-to-use syringe)			2 9	0 5	3 4	0 2
<b>8 rFVIII molecule</b>	<b>1%</b>		<b>0%</b>		<b>0%</b>	
Full length	1 1	0 2				
B-domain deleted	0 9	0 2				
Base	98		32		171	

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## **Trade-off / Conjoint analysis**

### **1. Background**

A common problem often encountered within the research arena is that of measuring the relative importance of attributes within a product. Trade-off analysis decomposes the product into a number of features or attributes. The respondents then trade-off these attributes against one another, forcing them to indicate their preferences. From this information, it is possible to establish the relative importance of each of the attributes – thus providing a wealth of useful, clear information and powerful modelling capabilities.

### **2. Full profile conjoint**

#### **2.1 Methodology**

A full profile conjoint technique is one whereby

- each attribute is further broken down into different levels,
- product concepts are formed by combining different attribute levels,
- respondents are presented with cards each containing different product concepts,
- respondents are asked to rank the cards in order of preference.

This forces respondents to trade-off all the attributes against one another at the same time.

#### **2.2 Analysis and utilities**

The full profile conjoint technique produces rankings for attribute combinations. Modelling techniques are then used to produce utilities for each level of each of the attributes. The utilities are measures of the value or attractiveness of each attribute level to respondents. They are calculated for each individual respondent. A measure of importance is also derived for each attribute. This shows how important the attribute is in the choice process. These are produced for the whole respondent set.

The utilities are used to

- identify the most popular options within an attribute – the greater the utility, the more popular the option or level,
- measure the importance of the attributes - the distance between the most and least popular levels within an attribute dictate the attribute's importance
- assess the value of different product combinations - the utilities are added

Having collected rankings on a small subset of all possible product concepts or combinations, we can calculate the relative preference for every possible product combination. This is done by simply adding together the utilities of each of the attribute levels within a product concept.

These product utilities can be calculated on an individual respondent basis. These can then be compared – the product with the highest utility will be the one that the respondent will prefer. Hence we can estimate market share for different products simulating the marketplace. We can fine-tune products to maximise market share or minimise cost whilst maintaining market share.